	SECURI	UNITED STATES TIES AND EXCHANGE COMMISS Washington, D.C. 20549 FORM 10-Q	SION		
(Mark One)	QUARTERLY REPORT PURSUANT TO SECTION 1	3 OR 15(d) OF THE SECURITIES E	XCHANGE ACT OF 1934		
		quarterly period ended September 30, 2			
	T of the c		-02 <del>1</del>		
		Or			
	TRANSITION REPORT PURSUANT TO SECTION 1	3 OR 15(d) OF THE SECURITIES EX	XCHANGE ACT OF 1934		
	For the trans	sition period from to			
	С	commission file number: 001-36333			
		Bio-Path Holdings, Inc. ame of registrant as specified in its cha	rter)		
	Delaware		87-0652870		
	(State or other jurisdiction of		(I.R.S. Employer		
	incorporation or organization)		Identification No.)		
	4710 Bellaire Boulevard, Suite 210, Bellaire, Texas	levard, Suite 210, Bellaire, Texas 77401			
	(Address of principal executive offices)		(Zip Code)		
		(832) 742-1357			
	(Registra	nt's telephone number, including area o	code)		
Securities reg	sistered 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		
			$5(d)$ of the Securities Exchange Act of 1934 during the preceding ubject to such filing requirements for the past 90 days. Yes $\boxtimes$ No		
-	neck mark whether the registrant has submitted electronic this chapter) during the preceding 12 months (or for such		ed to be submitted pursuant to Rule 405 of Regulation S-T required to submit such files). Yes $\boxtimes$ No $\square$		
			ed filer, a smaller reporting company, or an emerging growth ad "emerging growth company" in Rule 12b-2 of the Exchange		

Large accelerated filer  $\Box$ Non-accelerated filer  $\boxtimes$  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.  $\Box$ 

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

At November 8, 2024, the Company had 4,306,892 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	September 30, 2024 (unaudited)	As of December 31, 2023		
Assets		(unauditeu)			
Current assets					
Cash	\$	562	\$	1,052	
Prepaid drug product	+	531	*	632	
Other current assets		1,806		1,358	
Total current assets		2,899		3,042	
Fixed assets					
Furniture, fixtures & equipment		1,120		1,120	
Less accumulated depreciation		(1,078)		(1,044)	
		42		76	
Right of use operating assets		24		102	
Total Assets	\$	2,965	\$	3,220	
Liabilities & Shareholders' (Deficit) Equity					
Current liabilities					
Accounts payable	\$	1,036	\$	457	
Accrued expenses		2,313		1,346	
Current portion of lease liabilities		26		103	
Total current liabilities		3,375		1,906	
Warrant liability		302		863	
Noncurrent lease liabilities		_		10	
Total Liabilities		3,677		2,779	
Shareholders' (deficit) equity					
Preferred stock, \$.001 par value; 10,000 shares authorized; no shares issued and outstanding					
Common stock, \$.001 par value; 200,000 shares authorized; 3,710 and 618 shares issued and outstanding,					
respectively		4		1	
Additional paid in capital		114,032		108,047	
Accumulated deficit		(114,748)		(107,607)	
Total shareholders' (deficit) equity		(712)		441	
Total Liabilities & Shareholders' (Deficit) Equity	\$	2,965	\$	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 September 30,				Nine Months Ended September 30,					
		2024	2023			2024	2023			
Operating expenses										
Research and development	\$	1,317	\$	2,292	\$	5,478	\$	9,332		
General and administrative		1,317		984		3,889		3,478		
Total operating expenses		2,634		3,276		9,367		12,810		
Net operating loss	\$	(2,634)	\$	(3,276)	\$	(9,367)	\$	(12,810)		
Other income										
Change in fair value of warrant liability		515		72		2,216		72		
Interest income		4		5		10		32		
Total other income		519		77		2,226		104		
Net loss	\$	(2,115)	\$	(3,199)	\$	(7,141)	\$	(12,706)		
Net loss per share, basic and diluted	\$	(0.70)	\$	(6.36)	\$	(4.05)	\$	(29.34)		
Basic and diluted weighted average number of common shares outstanding		3,017		503		1,763		433		

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	Nine Mor	Nine Months Ended September			
	2024		2023		
Cash flow from operating activities					
Net loss	\$ (	7,141) \$	6 (12,706)		
Adjustments to reconcile net loss to net cash used in operating activities					
Stock-based compensation		439	554		
Amortization of right of use assets		78	71		
Depreciation		34	66		
Change in fair value of warrant liability	(	2,216)	(72)		
(Increase) decrease in operating assets	, in the second s		~ /		
Prepaid drug product		101	2,955		
Other current assets		(448)	(174)		
Increase (decrease) in operating liabilities					
Accounts payable and accrued expenses		1,546	(335)		
Lease liabilities		(87)	(80)		
Net cash used in operating activities	(	7,694)	(9,721)		
Cash flow from financing activities					
			4 600		
Net proceeds from sale of common stock		7,204	1,689		
Nister al marci la llas Complexes dividires		7 204	1 ( 00		
Net cash provided by financing activities		7,204	1,689		
Net increase (decrease) in cash		(490)	(8,032)		
Cash, beginning of period		1,052	10,384		
Cash, end of period	\$	562 \$	2,352		

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

Description	Common Stock Shares Amount			Additional Paid in Capital			Accumulated Deficit		Total
Description	Shares		ount		Capital		Denen		Iotai
Balance at June 30, 2023	398	\$	1	\$	106,078	\$	(101,036)	\$	5,043
Issuance of common stock and warrants, net of fees and warrant liability	175				503		_		503
Stock-based compensation	_		—		178		_		178
Net loss			—		—		(3,199)		(3,199)
Balance at September 30, 2023	573	\$	1	\$	106,759	\$	(104,235)	\$	2,525
Balance at June 30, 2024	2,283	\$	2	s	113,922	\$	(112,633)	\$	1,291
	2,200	φ	-	ų.	110,722	Ψ	(112,000)	Ψ	1,271
Issuance of common stock and warrants, net of fees and warrant liability	1,427		2		(18)		_		(16)
Stock-based compensation	—		—		128				128
Net loss			_				(2,115)		(2,115)
Balance at September 30, 2024	3,710	\$	4	\$	114,032	\$	(114,748)	\$	(712)

Description	Common Stock Shares Amount			Additional Paid in		Accumulated Deficit			Total
	Shares	All	iount		Capital	Delicit		_	Total
Balance at December 31, 2022	398	\$	1	\$	105,702	\$	(91,529)	\$	14,174
Issuance of common stock and warrants, net of fees and warrant liability	175				503				503
Stock-based compensation			_		554		_		554
Net loss			—		_		(12,706)		(12,706)
Balance at September 30, 2023	573	\$	1	\$	106,759	\$	(104,235)	\$	2,525
Balance at December 31, 2023	618	\$	1	\$	108,047	\$	(107,607)	\$	441
Issuance of common stock and warrants, net of fees and warrant liability	3,092		3		5,546				5,549
Stock-based compensation			_		439		_		439
Net loss							(7,141)		(7,141)
Balance at September 30, 2024	3,710	\$	4	\$	114,032	\$	(114,748)	\$	(712)

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 September 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 September 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 nine months ended September 30, 2024 and 2023. The calculation of diluted earnings per share for 2024 did not include 96,389 shares and 4,421,679 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of September 30, 2024 as the effect would be antidilutive. The calculation of diluted earnings

per share for 2023 did not include 43,383 shares and 234,688 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of September 30, 2023 as the effect would be antidilutive.

*Liquidity* - The Company's available cash and cash equivalents of \$0.6 million at September 30, 2024 along with the net proceeds received from the October 2024 Private Placement (see Note 12) 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 and incurred additional installment costs during the first nine months of 2024, with advanced payments remaining to be expensed totaling \$0.5 million as of September 30, 2024.

### 4. Other Current Assets

As of September 30, 2024, other current assets included prepaid expenses of \$1.8 million, comprised primarily of prepayments of \$1.4 million made for the Company's clinical trials for BP1001-A in solid tumors and BP1002 in separate clinical trials for AML and lymphoma. Additionally, the Company had prepaid insurance expenses of \$0.4 million. 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 September 30, 2024, current liabilities included accounts payable of \$1.0 million, comprised primarily of expenses related to clinical trial expenses of \$0.5 million, legal and patent fees of \$0.2 million, expenses related to the Company's recent financing activity of \$0.2 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 September 30, 2024, current liabilities included accrued expenses of \$2.3 million, comprised primarily of accrued clinical trial expenses of \$1.6 million, employee vacation and bonus expenses of \$0.3 million, professional and consulting fees of \$0.1 million, drug manufacturing development and testing services of \$0.1 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 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 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 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 September 30, 2024, the fair value of the total warrant liability was \$0.3 million. The net change in fair value for the three and nine months ended, September 30, 2024 was \$0.5 million, respectively, and are shown as other income on the Company's Condensed Consolidated Statements of Operations. 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 September 30, 2024:

	Fair Value Measurements at September 30, 2024 (in thousands)							
	 Level 1		Level 2		Level 3		Total	
Liabilities:								
Warrant liability	\$ 	\$		\$	302	\$	302	

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	\$		\$	<u> </u>	\$	863	\$	863	

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

	Fair Value of Warrant Liability
	(in thousands)
Balance at December 31, 2023	\$ 863
Issuance	1,655
Change in fair value	(2,216)
Balance at September 30, 2024	\$ 302

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

	As of
	September 30, 2024
Risk-free interest rate	3.58 %
Expected volatility	109 %
Expected term in years	4.4
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 175,000 shares of its common stock, together with warrants to purchase up to 175,000 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, which Initial ATM 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, 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 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 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' (Deficit) Equity totaled (\$0.7) million as of September 30, 2024 compared to \$0.4 million as of December 31, 2023. There were 3,710,190 shares of common stock issued and outstanding as of September 30, 2024. There were no shares of preferred stock issued and outstanding as of September 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 September 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 September 30, 2024 and 2023 was \$0.1 million and \$0.2 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended September 30, 2024 and 2023 was \$0.1 million and \$0.2 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended September 30, 2024 and 2023 was \$34,000 and \$45,000, respectively.

Stock-based compensation expense for the nine months ended September 30, 2024 and 2023 was \$0.4 million and \$0.6 million, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the nine months ended September 30, 2024 and 2023 was \$0.3 million and \$0.4 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for each of the nine months ended September 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, with the following weighted-average assumptions for options granted in the nine months ended September 30, 2024 and 2023:

	2024	2023
Risk-free interest rate	4.00 %	3.42 %
Expected volatility	134 %	129 %
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 nine months ended September 30, 2024:

	Options		Weighted- Average Exercise Price
	(in thousands)	¢	1(1.20
Outstanding at December 31, 2023	43	\$	161.20
Granted	53	\$	1.55
Outstanding at September 30, 2024	96	\$	71.40
Vested and expected to vest September 30, 2024	94	\$	72.74
Exercisable at September 30, 2024	34	\$	184.17

As of September 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 September 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 September 30, 2024. This amount changes based on the fair value of the Company's stock.

As of September 30, 2024, unamortized stock-based compensation expense for all outstanding options was \$0.5 million, which is expected to be recognized over a weighted average vesting period of 1.6 years.

#### 11. Commitments and Contingencies

*Drug Supplier Project Plan* – Total commitments for the Company's drug supplier project plan were \$0.8 million as of September 30, 2024, comprised of \$0.5 million for the manufacture of prexigebersen and BP1001-A drug products, \$0.2 million for manufacture of the Company's Grb2 drug substance and \$0.1 million for testing services. The Company expects to incur \$0.7 million of these commitments over the next 12 months.

### 12. Subsequent Events

**October 2024 Private Placement** – On October 8, 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) pre-funded warrants to purchase up to 4,597,702 shares of its common stock at an exercise price of \$0.001 per share, (ii) series A warrants to purchase up to 6,407,657 shares of its common stock at an exercise price of \$1.00 per share and (iii) series B warrants to purchase up to 6,407,657 shares of its common stock at an exercise price of \$1.00 per share and (iii) series B warrants to purchase up to 6,407,657 shares of its common stock at an exercise price of \$1.00 per share and (iii) certain private Placement"). The October 2024 Private Placement closed on October 10, 2024 (the "Closing Date"). In connection with the October 2024 Private Placement, the Company and the investor agreed to cancel such investor's series A warrants to purchase 1,809,955 shares of common stock at an exercise price of \$2.00 and series B warrants to purchase 1,809,955 shares of common stock at an exercise price of \$2.00 and series B closing Date. 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 \$3.4 million.

Lease – In October 2024, the Company entered into an amendment to the lease agreement for its administrative office space located in Bellaire, Texas to extend the term of the lease for a period of one year, beginning on November 1, 2024 and ending on October 31, 2025.

# 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 II of this Quarterly Report on Form 10-Q and our ended December 31, 2023, the matters discussed in "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-K as of the fiscal year ended looking statements for many reasons, including 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 in the use 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 to the treatment 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 venetoclaxresistant 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 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 (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 is reatment and/or for 22% for refractory/relapsed patients treated with the combination treatment and/or for the 14 evaluable refractory/relapsed patients in the second cohort is evaluable at the areage of 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 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 fobrile 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

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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 in 2026.

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<sup>2</sup>). Enrollment has continued for patients in the second BP1002 dose cohort of 40 mg/m<sup>2</sup>.

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. On October 7, 2024, we announced that the FDA had completed its review of PK/PD data from the first two dosing cohorts and that the enrollment for the third dosing cohort (60 mg/m<sup>2</sup>) is now complete. We expect to advance to the next planned higher dose of 90 mg/m<sup>2</sup> 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 gencitabine, a treatment for patients with advanced 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. On September 16, 2024, we announced a publication in the peer-reviewed journal, Biomedicines, which highlights the therapeutic potential and broad anti-tumor effect 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<sup>2</sup>, and there were no dose limiting toxicities. Enrollment is now open for patients for the second dose cohort of 90 mg/m<sup>2</sup> which we expect to be complete in the first quarter of 2025 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 generitabine in Stage 4 pancreatic cancer and combination therapy in breast cancer.

Grb2 is involved in activating the RAS/ERK pathway for cell growth. By blocking the cell's ability to produce Grb2, BP1001-A treatment may limit cell growth. In obesity, two such growth pathways are related to leptin and insulin. Activation of leptin or insulin receptors can stimulate the RAS/ERK pathway via Grb2. Developing BP1001-A for the treatment of obesity should have a high probability of success as its mechanism of action has the potential to treat insulin resistance, which is the major contributor to obesity, Type 2 diabetes and other related metabolic diseases. We believe development of BP1001-A for the treatment for obesity and related metabolic diseases could be accelerated given the large amount of safety data from BP1001-A treatment of patients with solid tumors and the continued unmet medical need. The Company is preparing for preclinical development evaluating BP1001-A for the treatment of obesity and will continue thereafter to conduct additional IND-enabling studies with an aim to advance BP1001-A into first-in-human studies in this indication.

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 September 30, 2024, we had an accumulated deficit of \$114.7 million. Our net loss was \$2.1 million and \$3.2 million for the three months ended September 30, 2024 and 2023, respectively. Our net loss was \$7.1 million and \$12.7 million for the nine months ended September 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 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 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 split-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 September 30, 2024 to the Three Months Ended September 30, 2023

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

Research and Development Expense. Our research and development expense for the three months ended September 30, 2024 was \$1.3 million, a decrease of \$1.0 million compared to the three months ended September 30, 2023. The decrease in research and development expense was primarily due to decreased manufacturing expenses related to drug product releases as well as a decrease in expense related to our clinical trial for BP1001 in AML due to timing of patient enrollment during the quarter. The following table sets forth our research and development expenses (in thousands):

	Three Months Ended September 30,		
	 2024		2023
Research and development expense	\$ 1,283	\$	2,247
Non-cash stock-based compensation expense	34		45
Total research and development expense	\$ 1,317	\$	2,292

*General and Administrative Expense.* Our general and administrative expense for the three months ended September 30, 2024 was \$1.3 million, an increase of \$0.3 million compared to the three months ended September 30, 2023. The increase in general and administrative expense was primarily due to increased legal fees and salaries and benefits expense. The following table sets forth our general and administrative expenses (in thousands):

	Three Months Ended September 30,		
	 2024		2023
General and administrative expense	\$ 1,223	\$	851
Non-cash stock-based compensation expense	94		133
Total general and administrative expense	\$ 1,317	\$	984

Net Operating Loss. Our net loss from operations for the three months ended September 30, 2024 was \$2.6 million, a decrease of \$0.6 million compared to the three months ended September 30, 2023.

Change in Fair Value of Warrant Liability: The change in fair value of the warrant liability for the three months ended September 30, 2024 resulted in non-cash income of \$0.5 million.

Net Loss. Our net loss for the three months ended September 30, 2024 was \$2.1 million, a decrease of \$1.1 million compared to the three months ended September 30, 2023.

*Net Loss per Share.* Net loss per share, both basic and diluted, for the three months ended September 30, 2024 was \$0.70, compared to \$6.36 for the three months ended September 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 Nine Months Ended September 30, 2024 to the Nine Months Ended September 30, 2023

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

Research and Development Expense. Our research and development expense for the nine months ended September 30, 2024 was \$5.5 million, a decrease of \$3.9 million compared to the nine months ended September 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):

	Nine Months Ended September 30,		
	 2024		2023
Research and development expense	\$ 5,364	\$	9,195
Non-cash stock-based compensation expense	114		137
Total research and development expense	\$ 5,478	\$	9,332

General and Administrative Expense. Our general and administrative expense for the nine months ended September 30, 2024 was \$3.9 million, an increase of \$0.4 million compared to the nine months ended September 30, 2023. The increase in general and administrative expense was primarily due to increased legal fees and salaries and benefits expense. The following table sets forth our general and administrative expenses (in thousands):

	Nine Months Ended September 30,		
	 2024		2023
General and administrative expense	\$ 3,564	\$	3,061
Non-cash stock-based compensation expense	325		417
Total general and administrative expense	\$ 3,889	\$	3,478

Net Operating Loss. Our net loss from operations for the nine months ended September 30, 2024 was \$9.4 million, a decrease of \$3.4 million compared to the nine months ended September 30, 2023.

Change in Fair Value of Warrant Liability: The change in fair value of the warrant liability for the nine months ended September 30, 2024 resulted in non-cash income of \$2.2 million.

Net Loss. Our net loss for the nine months ended September 30, 2024 was \$7.1 million, a decrease of \$5.6 million compared to the nine months ended September 30, 2023.

*Net Loss per Share.* Net loss per share, both basic and diluted, for the nine months ended September 30, 2024 was \$4.05, compared to \$29.34 for the nine months ended September 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 \$0.6 million as of September 30, 2024, a decrease of \$0.5 million compared to December 31, 2023. We do not believe that our available cash at September 30, 2024, together with the net proceeds received from the October 2024 Private Placement (as defined 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 to meet its planned obligations and pay its liabilities.

#### Cash Flows

*Operating Activities.* Net cash used in operating activities for the nine months ended September 30, 2024 was \$7.7 million. Excluding non-cash change in fair value of the warrant liability of \$2.2 million, 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 nine months ended September 30, 2024 consisted primarily of the net loss for the period of \$7.1 million, an increase other current assets of \$0.4 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 \$1.5 million and a decrease in prepaid drug product of \$0.1 million. Net cash used in operating activities for the nine months ended September 30, 2023 was \$9.7 million. Excluding non-cash stock-based compensation expenses of \$0.1 million. Net cash used in operating activities for the nine months ended September 30, 2023 was \$9.7 million. Excluding non-cash stock-based compensation expenses of \$0.6 and depreciation and amortization expenses of \$0.1 million. Net cash used in operating activities for the nine months ended September 30, 2023 was \$9.7 million. Excluding non-cash stock-based compensation expenses of \$0.6 and depreciation and amortization expenses of \$0.1 million, net loss, net cash used in operating activities for the nine months ended September 30, 2023 consisted primarily of the net loss for the period of \$1.2.7 million, a decrease in operating liabilities of \$0.4 million and an increase in other current assets of \$0.2 million. These are partially offset by a decrease in prepaid drug product of \$3.0 million.

*Financing Activities.* Net cash provided by financing activities for the nine months ended September 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). Net cash provided by financing activities for the nine months ended September 30, 2023 was \$1.7 million from the 2023 Public Offering (as defined below).

#### 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 175,000 shares of our common stock, together with warrants to purchase up to 175,000 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, we offered and sold 436,511 shares of common stock for gross proceeds of approximately \$2.0 million and terminated the offering agreement 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"). As of September 30, 2024, we have 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.

#### **October 2024 Private Placement**

On October 8, 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) pre-funded warrants to purchase up to 4,597,702 shares of our common stock at an exercise price of \$0.001 per share, (ii) series A warrants to purchase up to 6,407,657 shares of our common stock at an exercise price of \$1.00 per share and (iii) series B warrants to purchase up to 6,407,657 shares of our common stock at an

exercise price of \$1.00 per share for gross proceeds of approximately \$4.0 million (the "October 2024 Private Placement"). The October 2024 Private Placement closed on October 10, 2024 (the "Closing Date"). In connection with the October 2024 Private Placement, the Company and the investor agreed to cancel such investor's series A warrants to purchase 1,809,955 shares of common stock at an exercise price of \$2.00 and series B warrants to purchase 1,809,955 shares of common stock at an exercise price of \$2.00 issued to such investor in connection with the June 2024 PIPE, effective as of the Closing Date. 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 \$3.4 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 September 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, and 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.

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# 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, Bio-Path Holdings, Inc. (the "Company") received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("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 and 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.

On September 12, 2024, the Company received a delisting determination letter from Nasdaq advising the Company that the Company did not meet the terms of the Extension Letter. Specifically, the Company did not confirm or demonstrate compliance with the Stockholders' Equity Requirement by completing its proposed transactions as set forth in the Extension Letter. On September 19, 2024, the Company submitted a hearing request to the Nasdaq Hearings Panel (the "Panel"), which request stayed suspension of the Company's securities and the filing of the Form 25-NSE pending the Panel's decision. On September 19, 2024, the Company received a letter from Nasdaq accepting the request for appeal and scheduling the hearing date for November 5, 2024. At the Panel hearing, the Company intends to present a plan to regain compliance with the Stockholders' Equity Requirement. In the interim, the Company's common stock will continue to trade on the Nasdaq Capital Market under the symbol "BPTH" pending the Panel's decision. There can be no assurance that the Company's appeal will be successful or that the Company will be able to regain compliance with the Stockholders' Equity Requirement.

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
<u>2.1</u>	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).
<u>3.1</u>	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).
<u>3.2</u>	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).
<u>3.3</u>	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).
<u>3.4</u>	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).
<u>3.5</u>	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).
<u>3.6</u>	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).
<u>4.1</u>	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 11, 2024).
<u>4.2</u>	Form of Series A Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 11, 2024).
<u>4.3</u> <u>4.4</u>	Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on October 11, 2024).
<u>4.4</u>	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on October 11, 2024).
<u>10.1</u>	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 11, 2024).
<u>10.2</u>	Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 11, 2024).
<u>10.3*</u>	Second Amendment to Lease Agreement, dated October 23, 2024, by and between the Company and the registered holders of GS Mortgage Securities
	Corporation II, Commercial Mortgage Pass-Through Certificates, Series 2018-GS9, and the RR Interest Owner v. Norvin Pin Oak North LLC, et al., Case
	<u>No.: 2024-369993.</u>
<u>31*</u>	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.
<u>32**</u>	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 September 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
10.4*	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 September 30, 2024, formatted in Inline XBRL (included as
* Filed	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: November 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)

# SECOND AMENDMENT TO LEASE AGREEMENT

This Second Amendment to Lease Agreement (this "Amendment") is made and entered on October 23, 2024, by and between MARK FOWLER, an individual, NOT IN HIS OWN RIGHT BUT SOLELY IN HIS CAPACITY AS COURT APPOINTED RECEIVER, pursuant to that certain Agreed Order Appointing Receiver (the "Order") entered June 13, 2024, by the 61st Judicial District Court, County of Harris, State of Texas, in case captioned Wilmington Trust, National Association, as Trustee, for the benefit of the registered holders of GS Mortgage Securities Corporation II, Commercial Mortgage Pass-Through Certificates, Series 2018-GS9, and the RR Interest Owner v. Norvin Pin Oak North LLC, et al., Case No.: 2024-369993 (together with his successors and/or assigns, "Receiver" and/or "Lessor," as the case may be) and BIO-PATH HOLDINGS, INC., a Delaware corporation ("Lessee").

# WITNESSETH:

WHEREAS, by that certain Lease Agreement dated effective April 9, 2014 (the "Original Lease"), Pin Oak North Parcel TT, LLC, as lessor, leased to Lessee certain lease space known as Suite 210 located on the 2nd floor of the building located at 4710 Bellaire Boulevard, Bellaire, Harris County, Texas 77401 (the "Building"), all as is more fully described in the Original Lease;

WHEREAS, the Original Lease was amended by that certain First Amendment to Lease Agreement dated May 29, 2019, hereinafter the "First Amendment";

WHEREAS, the Original Lease and First Amendment, including all addendums, riders, and exhibits thereto, are hereinafter collectively referred to as the "Lease Agreement";

WHEREAS, the leased premises defined in the Lease Agreement as Suite 210 which contains approximately 3,002 square feet is hereinafter referred to as the "Leased Premises";

WHEREAS, the Leased Premises and the Building are subject to a lien as a security for a loan (the "Loan") made to Norvin Pin Oak North LLC, Norvin Pin Oak North II LLC, Norvin Pin Oak North II LLC, Norvin Pin Oak North V LLC, and Norvin Pin Oak North VI LLC, Delaware limited liability companies;

WHEREAS, in connection with the Loan, the current holder of the Loan requested the appointment of a receiver for the real property known as "the Pin Oak North Office complex" and having a street address of 6700 & 6750 West Loop South and 4710 Bellaire Boulevard, Bellaire, Texas 77401, which includes the Building and the Leased Premises;

WHEREAS, pursuant to the Order, Receiver has the authority to, among other things, enter into this Amendment;

WHEREAS, the Lease Agreement has an expiration date of October 31, 2024;

WHEREAS, Receiver, as lessor, and Lessee desire to amend the Lease Agreement to extend the Lease Agreement term by twelve (12) months, commencing on November 1, 2024 (the "Commencement Date"); and

WHEREAS, Receiver, as lessor, and Lessee now desire to amend the Lease Agreement in order to modify certain provisions of the Lease Agreement to reflect the above.

# **AGREEMENT**

NOW, THEREFORE, for and in consideration of the covenants and mutual benefits to be derived by the parties hereto from the matters set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged and confessed, Lessor and Lessee agree to amend the Lease Agreement as follows:

# 1. <u>Term</u>.

IT IS AGREED that all references contained in the Lease Agreement to Lessee's expiration date, including those mentioned in Section 2 (entitled "Term"), and any other provision wherein reference is made to Lessee's expiration date for the Lease Agreement shall hereinafter refer to an expiration date of October 31, 2025 (the "Expiration Date"). This amendment reflects the parties' agreement to extend the Lease Agreement term by twelve (12) months, commencing on the Commencement Date. Tenant shall have no further option to extend or renew the Term.

# 2. <u>Condition of Leased Premises</u>.

Lessee is currently in occupancy of the Leased Premises. In regards to the Leased Premises, it is understood and agreed that Lessee accepts the Leased Premises in its "AS IS" condition. Lessee agrees that Lessor has not made any warranties to Lessee with respect to the quality of construction of any existing leasehold improvements or as to the condition of the Leased Premises except as may be expressly set forth in this Amendment, either expressed or implied. Lessor hereby expressly disclaims any implied warranties that the Leased Premises are or will be suitable for Lessee's "intended commercial purpose."

# 3. Base Rent.

IT IS FURTHER AGREED that all references contained in the Lease Agreement to Base Rent, including but not limited to those references contained within Section 5 thereof (entitled "Base Rent"), and any other provision wherein reference is made to the amount of monthly base rental owed by Lessee to Lessor shall hereinafter refer to an amount of monthly Base Rent for the Leased Premises for the periods as follows:

Period	Monthly Installment of Base Rent
November 1, 2024 – October 31, 2025	\$7,582.08

The monthly Base Rent as amended is in addition to Lessee's proportionate share of Basic Costs as defined in

the Lease Agreement.

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# 4. Late Fee.

IT IS FURTHER AGREED that the first sentence of the second paragraph in Section 5 of the Lease Agreement is hereby deleted and replaced with the following:

"After the fifth (5<sup>th</sup>) day of the month in which rent is due, rent shall be considered delinquent and Lessee shall be required to pay Lessor a sum equal to ten percent (10%) of such monthly rental required to be paid by Lessee to Lessor under the terms hereof."

This amendment reflects the parties' agreement to increase the late fee to ten percent (10%). No other changes to this Section are affected by this amendment.

# 5. <u>Notices</u>.

IT IS FURTHER AGREED that the Lease Agreement regarding addresses for notices is hereby amended to revise Lessor's new addresses for notice as follows:

To the Lessor: Mark Fowler, as Receiver c/o Transwestern 1900 West Loop South, Suite 1300 Houston, Texas 77027

> With a copy to: Locke Lord LLP Attn: Ryan Morgan 600 Travis, Suite 2800 Houston, Texas 77002

With copy to: Norvin Pin Oak North LLC 845 Third Ave, 6<sup>th</sup> Floor, Suite 132 New York, NY 10022

With copy to: Norvin Pin Oak North LLC c/o Transwestern 4747 Bellaire, Suite 515 Bellaire, Texas 77401 Atten: Manager

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6. <u>Security Deposit</u>. Lessee's security deposit in the amount of \$7,319.88 shall remain on file for the Term.

7. <u>Parking</u>. Tenant shall continue to have the parking rights as set forth in Section 5 of the First Amendment for the remainder of the Term, as extended herein.

# 8. <u>Miscellaneous</u>.

(a) All the terms of the Lease Agreement not otherwise modified or changed by this document shall remain in full force and effect, according to the terms thereof. Lessor and Lessee hereby ratify and confirm the Lease Agreement as amended hereby. Lessee expressly states that at this time, Lessor is not in default on the terms of the Lease Agreement. Lessor expressly states that at this time, Lessee is not in default on the terms of the Lease Agreement.

(b) Lessor and Lessee expressly acknowledge that the Lease Agreement as amended represents the entire agreement between Lessor and Lessee.

(c) Lessor and Lessee each represent and warrant that the party executing this document on behalf of such party possesses all lawful rights and authority to enter into this document on behalf of that party; that there are no judgments, decrees, or outstanding orders of any court prohibiting the execution of this document; and that all required approvals, consents and resolutions necessary to effectuate the terms and provisions of this document have been obtained.

(d) Lessor and Lessor's agents and Lessee and Lessee's agents have made no representations or promises, express or implied, in connection with this document except as expressly set forth herein.

(e) The section headings contained in this document are for convenience only and shall in no way enlarge or limit the scope or meaning of the various and several sections hereof.

(f) All terms not otherwise defined herein shall have the same meaning assigned to them in the Lease Agreement.

(g) Lessor and Lessee agree that each provision of the Lease Agreement (as amended by this Amendment) for determining charges, amounts, and expenses payable by Lessee is commercially reasonable and, as to each such charge or amount, constitutes a "method by which the charge is to be computed" for purposes of Section 93.012 of the Texas Property Code.

(h) Lessor and Lessee each warrants to the other that it has had no dealings with any real estate broker or agent in connection with the negotiation of this document, excepting only CBRE, Inc. ("Lessor's Broker") and Transwestern Property Company SW GP, L.L.C. d/b/a Transwestern ("Lessee's Broker"). Lessee agrees to indemnify, defend (with counsel reasonably acceptable to Lessor) and hold harmless the Lessor Parties, and Lessor agrees to indemnify, defend (with counsel reasonably acceptable to Lessee) and hold harmless Lessee from and against any liability from all other claims for commissions arising out of or resulting from claims for commissions or fees by any person claiming by, through or under such indemnifying party in connection with this Amendment (other than Lessor's Broker and Lessee's Broker). Lessor agrees to pay Lessor's Broker and Lessee's Broker a commission pursuant to separate written agreements.

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(i) Receiver has been appointed as the court-appointed receiver of the Land and all improvements thereon pursuant to the Order. All actions and deeds of Receiver in connection with the transactions contemplated by this Amendment are solely in his capacity as Receiver, as defined in the Order, and all subsequent orders and supplements thereto. The parties hereto agree that Receiver, individually, shall have no personal liability. The burdens and liabilities of the Lease Agreement, as amended by this Amendment, shall extend to Receiver in his capacity as receiver only, as defined and limited by the Order, as amended or supplemented, and not in his individual capacity. In no event shall Receiver have liability if Receiver is acting pursuant to a court order or, in any event, liability in excess of the liability set forth in the Order. Lessee agrees to look solely to Receiver to the extent of Receiver's interest in the Land and all improvements thereon for the satisfaction of any liability or obligation arising under the Lease Agreement, as amended by this Amendment, or the transactions contemplated hereby, or for the performance of any of the covenants, warranties, obligations or other agreements contained in the Lease Agreement, as amended by this Amendment, and further agrees not to sue or otherwise seek to enforce any personal obligation against any of Receiver's assets, other than Receiver's interest in the Land and all improvements thereon with respect to any matters arising out of or in connection with the Lease Agreement, as amended by this Amendment, or the duties and obligations contemplated thereby or hereby.

EXECUTED in multiple counterparts, each of which shall have the full force and effect of an original. In the event that any signature is delivered by e-mail delivery of an electronic format data file (i.e. .pdf), such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page was an original thereof. If so executed, each of such counterparts is to be deemed an original for all purposes, and all such counterparts shall, collectively, constitute one agreement. This Amendment shall be effective as of the Effective Date.

# SIGNATURE PAGES FOLLOW:

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# LESSOR:

# /s/ Mark Fowler

# MARK FOWLER,

an individual, NOT IN HIS OWN RIGHT BUT SOLELY IN HIS CAPACITY AS COURT APPOINTED RECEIVER, pursuant to that certain Agreed Order Appointing Receiver entered June 13, 2024, by the 61st Judicial District Court, County of Harris, State of Texas, in case captioned Wilmington Trust, National Association, as Trustee, for the benefit of the registered holders of GS Mortgage Securities Corporation II, Commercial Mortgage Pass-Through Certificates, Series 2018-GS9, and the RR Interest Owner v. Norvin Pin Oak North LLC, et al., Case No.: 2024-369993

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# LESSEE: BIO-PATH HOLDINGS, INC., a Delaware corporation

By: <u>/s/ Peter Nielsen</u>

Name: Peter Nielsen

Title: President and Chief Executive Officer <u>SECOND AMENDMENT TO LEASE AGREEMENT</u> – Signature Page

# 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: November 14, 2024

By: /s/ Peter H. Nielsen

Peter H. Nielsen Chief Executive Officer (Principal Executive Officer) Chief Financial Officer (Principal Financial Officer)

### 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 September 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: November 14, 2024

By: /s/ Peter H. Nielsen

Peter H. Nielsen Chief Executive Officer Chief Financial Officer