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

(Mark One)

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

For the quarterly period ended September 30, 2019

Or

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

For the transition period from __ to __

Commission file number: 001-36333

Bio-Path Holdings, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

At November 1, 2019, the Company had 2,883,777 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 wholly-owned subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "project," "goal," "strategy," "future," "likely," "may," "should," "will" and variations of these words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances, including those discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2018, and in other reports or documents we file with the U.S. Securities and Exchange Commission ("SEC"). As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. Please 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, 2018, 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. 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. Forward-looking statements include, but are not limited to, statements about:

- 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;
- 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 that our clinical trials may be delayed or terminated;
- our ability to obtain domestic and 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;
- 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;
- a material weakness identified in our internal controls over financial reporting; and
- our ability to maintain compliance with the listing standards of the Nasdaq Capital Market.

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)
(Unaudited)

	As of September 30, 2019	As of December 31, 2018
Assets		
Current assets		
Cash	$ 15,382	$ 1,004
Prepaid drug product for testing	765	332
Other current assets	739	803
Total current assets	16,886	2,139
Fixed assets		
Furniture, fixtures & equipment	1,029	998
Less accumulated depreciation	(708)	(592)
	321	406
Right of use operating assets	388	-
Total Assets	$ 17,595	$ 2,545
Liabilities & Shareholders' Equity		
Current liabilities		
Accounts payable	$ 522	$ 587
Accrued expenses	618	740
Current portion of lease liabilities	79	-
Total current liabilities	1,219	1,327
Noncurrent lease liabilities	352	-
Total Liabilities	1,571	1,327
Shareholders' equity		
Preferred stock, $.001 par value; 10,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $.001 par value; 200,000 shares authorized; 2,884 and 680 shares issued and outstanding, respectively	3	1
Additional paid in capital	69,971	48,957
Accumulated deficit	(53,950)	(47,740)
Total shareholders' equity	16,024	1,218
Total Liabilities & Shareholders' Equity	$ 17,595	$ 2,545

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	
	2019	**2018**	**2019**	**2018**
Operating expenses				
Research and development	$ 1,375	$ 2,342	$ 3,296	$ 4,101
General and administrative	896	740	2,984	2,579
Total operating expenses	2,271	3,082	6,280	6,680
Net operating loss	$ (2,271)	$ (3,082)	$ (6,280)	$ (6,680)
Other income (loss)				
Interest income	29	1	70	6
Total other income	29	1	70	6
Net loss	$ (2,242)	$ (3,081)	$ (6,210)	$ (6,674)
Net loss per share, basic and diluted	$ (0.78)	$ (5.38)	$ (2.51)	$ (11.73)
Basic and diluted weighted average number of common shares outstanding	2,872	573	2,471	569

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flow from operating activities		
Net loss	$ (6,210)	$ (6,674)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	522	416
Amortization of technology license	-	121
Amortization of right of use assets	75	-
Depreciation	116	198
(Increase) decrease in operating assets		
Prepaid drug product for testing	(433)	860
Other current assets	64	72
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	(187)	166
Lease liabilities	(63)	-
Net cash used in operating activities	(6,116)	(4,841)
Cash flow from investing activities		
Purchases of furniture, fixtures & equipment	-	(17)
Net cash used in investing activities	-	(17)
Cash flow from financing activities		
Net proceeds from sale of common stock	19,411	1,179
Net proceeds from exercise of warrants	1,083	-
Net cash provided by financing activities	20,494	1,179
Net increase (decrease) in cash	**14,378**	**(3,679)**
Cash, beginning of period	1,004	5,965
Cash, end of period	$ 15,382	$ 2,286
Supplemental disclosure of non-cash activities		
Non-cash investing activities		
Non-cash leasehold improvements	$ (31)	$ -

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at June 30, 2018	**567**	**$ 1**	**$ 47,486**	**$ (42,750)**	**$ 4,737**
Issuance of common stock, net of fees	98	-	1,179	-	1,179
Stock-based compensation	-	-	153	-	153
Net loss	-	-	-	(3,081)	(3,081)
Balance at September 30, 2018	**665**	**$ 1**	**$ 48,818**	**$ (45,831)**	**$ 2,988**
Balance at June 30, 2019	**2,831**	**$ 3**	**$ 69,618**	**$ (51,708)**	**$ 17,913**
Exercise of warrants, net of fees	53	-	169	-	169
Stock-based compensation	-	-	184	-	184
Net loss	-	-	-	(2,242)	(2,242)
Balance at September 30, 2019	**2,884**	**$ 3**	**$ 69,971**	**$ (53,950)**	**$ 16,024**

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at December 31, 2017	**567**	**$ 1**	**$ 47,223**	**$ (39,157)**	**$ 8,067**
Issuance of common stock, net of fees	98	-	1,179	-	1,179
Stock-based compensation	-	-	416	-	416
Net loss	-	-	-	(6,674)	(6,674)
Balance at September 30, 2018	**665**	**$ 1**	**$ 48,818**	**$ (45,831)**	**$ 2,988**
Balance at December 31, 2018	**680**	**$ 1**	**$ 48,957**	**$ (47,740)**	**$ 1,218**
Issuance of common stock, net of fees	1,794	2	19,409	-	19,411
Exercise of warrants, net of fees	410	-	1,083	-	1,083
Stock-based compensation	-	-	522	-	522
Net loss	-	-	-	(6,210)	(6,210)
Balance at September 30, 2019	**2,884**	**$ 3**	**$ 69,971**	**$ (53,950)**	**$ 16,024**

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements
for the Period Ended September 30, 2019

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 interim financial statements have been prepared 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 necessary for a complete presentation of the Company's financial position, results of operations, cash flows, and stockholders' equity in conformity with generally accepted accounting principles. 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, 2018. The results of operations for the period ended September 30, 2019, 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. 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 neutral charged lipid bilayer. 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. DNAbilize® is a registered trademark of the Company. Using DNAbilize® as a platform for drug development and manufacturing, we currently have three antisense drug candidates in development to treat at least five different cancer disease indications.

Bio-Path Subsidiary was founded in May 2007 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 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. 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.

In June 2015, the Company established an "at the market" ("ATM") program through which it may offer and sell up to $25.0 million of its common stock from time to time, at Bio-Path's discretion, through an investment banking firm, acting as sales agent. Sales of Bio-Path common stock under the ATM program will be made directly on or through The Nasdaq Capital Market, among other methods. The ATM program may be terminated by either the investment banking firm or the Company upon ten days' notice. We are subject to certain restrictions on our ability to offer and sell shares of our common stock under the ATM program. To date, the Company has not offered or sold any shares of its common stock under the ATM program.

On September 20, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell an aggregate of 98,454 shares of our common stock and pre-funded warrants to purchase up to 14,624 shares of our common stock for gross proceeds of approximately $1.5 million under our effective shelf registration statement on Form S-3 (File No. 333-2152051) (the "2017 Shelf Registration Statement"), which became effective on January 9, 2017 (the "2018 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 113,077 shares of our common stock (the "2018 Private Placement"). Additionally, we issued warrants to purchase up to 6,785 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the 2018 Registered Direct Offering and the 2018 Private Placement. The 2018 Registered Direct Offering and the 2018 Private Placement closed on September 25, 2018. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $1.2 million.

On January 14, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC relating to an underwritten public offering of 429,616 shares of our common stock for gross proceeds of approximately $1.1 million under the 2017 Shelf Registration Statement (the "2019 Underwritten Offering"). The offering price to the public in the 2019 Underwritten Offering was $2.60 per share, and H.C. Wainwright & Co., LLC agreed to purchase the shares in the 2019 Underwritten Offering from the Company pursuant to the underwriting agreement at a price of $2.418 per share. Additionally, we issued warrants to purchase up to 25,777 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as underwriter in connection with the 2019 Underwritten Offering. The 2019 Underwritten Offering closed on January 17, 2019. The net proceeds to the Company from the 2019 Underwritten Offering, after deducting the underwriting discounts and commissions and expenses and the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the underwriter warrants, were approximately $0.9 million.

On January 17, 2019, 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 January 18, 2019. All common stock share and per share amounts in our consolidated financial statements have been adjusted to give effect to the 1-for-20 reverse stock split.

On January 18, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 648,233 shares of our common stock for gross proceeds of approximately $1.7 million under the 2017 Shelf Registration Statement (the "January 2019 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 324,117 shares of our common stock (the "January 2019 Private Placement"). Additionally, we issued warrants to purchase up to 38,894 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the 2019 Registered Direct Offering and the 2019 Private Placement. The 2019 Registered Direct Offering and the 2019 Private Placement closed on January 23, 2019. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $1.5 million.

On March 12, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 712,910 shares of our common stock for gross proceeds of approximately $18.5 million under the 2017 Shelf Registration Statement (the "March 2019 Registered Direct Offering"). Additionally, we issued warrants to purchase up to 42,775 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the March 2019 Registered Direct Offering. The March 2019 Registered Direct Offering closed on March 14, 2019. The net proceeds to us from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $17.0 million.

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

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability initially measured at the present value of the lease payments on the balance sheet for all leases with terms longer than 12 months. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In 2018, the FASB issued ASU 2018-01 and ASU 2018-11, which collectively adds two practical expedients and provides a second modified retrospective transition method in the year of adoption. Management adopted the new standard on January 1, 2019 using the modified retrospective transition approach with no restatement of prior periods or cumulative adjustment to accumulated deficit. We elected the "package of practiced expedients", which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and indirect costs. We also elected the short-term lease exemption and therefore do not recognize ROU assets or corresponding liabilities for lease agreements with an original term of 12 months or less. Consequently, prior year financials statements have not been updated and the disclosures required under the new standard have not been provided for periods prior to the adoption date. Upon adoption of the new standards, the Company recognized $0.1 million for ROU assets and corresponding lease liabilities on the consolidated balance sheet related to leases for office and lab space. The adoption of these ASU's on January 1, 2019 did not have a significant impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. The new standard eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. Management is currently evaluating the impact of future adoption of the new standard on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606.* The new standard provides guidance on how to assess whether certain transactions between collaborative arrangement participants should be accounted for within the revenue recognition standard. The update also provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. The new standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The Company early adopted this standard effective December 31, 2018 and notes that it did not a significant impact on our consolidated financial statements as the Company currently does not have significant collaborative agreements in place.

Management has reviewed all other recently issued pronouncements and has determined they will have no material impact on the Company's consolidated financial statements.

Correction of Immaterial Errors in Previously Issued Financial Statements

In evaluating the consolidated financial statements as of and for the years ended December 31, 2018, the Company subsequently identified immaterial errors within the Company's consolidated balance sheets as of December 31, 2018 and consolidated statements of cash flows for the year ended December 31, 2018. Reclassified amounts were determined to be immaterial and did not have an impact on cash flows from operating activities or the Company's results of operations for the year ended December 31, 2018.

3. Prepaid Drug Product for Testing

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 $0.3 million through 2018 pursuant to drug supply contracts for the manufacture and delivery of prexigebersen for testing in two Phase 2 clinical trials and Bcl-2 for testing in a Phase 1 clinical trial. This amount was carried on the Balance Sheet as of December 31, 2018 at cost as Prepaid Drug Product for Testing. The Company recognized certain expenses and incurred additional installment costs during 2019, with advanced payments totaling $0.8 million, which are carried on the Balance Sheet as of September 30, 2019 as Prepaid Drug Product for Testing (See Note 9).

4. Other Current Assets

As of September 30, 2019, Other Current Assets included prepaid expenses of $0.7 million, comprised primarily of prepayments made for our clinical trials for prexigebersen in AML and CML of $0.4 million and prepaid insurance of $0.3 million. As of December 31, 2018, Other Current Assets included prepaid expenses of $0.8 million, comprised primarily of prepayments made for our clinical trial for prexigebersen in AML of $0.6 million, prepaid insurance of $0.1 million and other prepaid expenses of $0.1 million.

5. Accounts Payable

As of September 30, 2019, Current Liabilities included accounts payable of $0.5 million, comprised primarily of amounts owed for external research expenses related to manufacturing and preclinical studies of $0.4 million and $0.1 million, respectively. As of December 31, 2018, Current Liabilities included accounts payable of $0.6 million, comprised primarily of preclinical expenses of $0.2 million, amounts owed to the Company's clinical research organizations for our clinical trials for prexigebersen in AML and CML of $0.1 million, an annual license maintenance fee of $0.1 million, manufacturing costs of $0.1 million and other payables of $0.1 million.

6. Accrued Expense

As of September 30, 2019, Current Liabilities included accrued expenses of $0.6 million, comprised primarily of accrued employee vacation and bonus expenses of $0.3 million, clinical and preclinical expenses of $0.2 million and other accrued expenses of $0.1 million. As of December 31, 2018, Current Liabilities included accrued expenses of $0.7 million, comprised primarily of accrued clinical and preclinical expenses of $0.5 million, employee vacation and bonus expenses of $0.1 million and legal and professional fees of $0.1 million.

7. Stockholders' Equity

Stockholders' Equity totaled $16.0 million as of September 30, 2019 compared to $1.2 million as of December 31, 2018. There were 2,883,777 shares of common stock issued and outstanding as of September 30, 2019. There were no preferred shares outstanding as of September 30, 2019.

8. Stock-Based Compensation Plan

The 2017 Plan – On December 21, 2017, the Company's stockholders approved the Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (the "2017 Plan"), which replaced the First Amended 2007 Stock Incentive Plan, as amended (the "2007 Plan"). The 2007 Plan expired by its terms in January 2018, and no awards were made under the 2007 Plan from the approval of the 2017 Plan on December 21, 2017 until the expiration of the 2007 Plan. The 2017 Plan provides for the grant of Incentive Stock Options, Non-Qualified Stock Options, Restricted Shares, Restricted Share Units, Stock Appreciation Rights, Performance-Based Awards 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, 2018, the total number of shares reserved and available for grant and issuance pursuant to the 2017 Plan was 60,000 shares, subject to the terms of the 2017 Plan. Under the 2017 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 intended to qualify as qualified Incentive Stock 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 2017 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 of control, as defined in the 2017 Plan.

Stock-based compensation expense for both the three months ended September 30, 2019 and September 30, 2018 was $0.2 million. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the three months ended September 30, 2019 and September 30, 2018 was $0.2 million and $0.1 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended September 30, 2019 and September 30, 2018 was $24,000 and $22,000, respectively.

Stock-based compensation expense for the nine months ended September 30, 2019 and September 30, 2018 was $0.5 million and $0.4 million, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for both the nine months ended September 30, 2019 and September 30, 2018 was $0.4 million. Stock-based compensation expense for personnel involved in the Company's research and development activities for both the nine months ended September 30, 2019 and September 30, 2018 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, 2019 and 2018, respectively:

	2019	2018
Risk-free interest rate	2.23%	2.70%
Expected volatility	126%	90%
Expected term in years	6.0	6.1
Dividend yield	-%	-%

The following summary represents option activity under the Company's stock-based compensation plans for the nine months ended September 30, 2019:

	Options (in thousands)	Weighted-Average Exercise Price
Outstanding at December 31, 2018	37	$ 112.60
Granted	35	18.40
Cancelled	(2)	41.28
Outstanding at September 30, 2019	70	67.71
Exercisable at September 30, 2019	25	$ 139.48

As of September 30, 2019, the aggregate intrinsic value of outstanding stock options was none. The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on September 30, 2019 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, 2019. This amount changes based on the fair market value of the Company's stock.

As of September 30, 2019, unamortized stock-based compensation expense for all outstanding options was $0.8 million, which is expected to be recognized over a weighted average vesting period of 2.2 years.

9. Commitments and Contingencies

Drug Supplier Project Plan – The amounts paid for manufacture of the Company's Grb2 drug substance, prexigebersen, Bcl-2 drug substance and BP1002 drug product that have not been expensed total $0.8 million and are carried on the balance sheet as of September 30, 2019 as Prepaid Drug Product for Testing (See Note 3). Total commitments for the Company's drug supplier project plan are $1.4 million as of September 30, 2019, comprised of $0.9 million to the manufacturer of prexigebersen and BP1002 drug product, $0.4 million for manufacture of our Grb2 and Bcl-2 drug substances, and $0.1 million for manufacturing development. We expect to incur $0.8 million of these commitments over the next 12 months.

10. Leases

In April 2014, the Company entered into a five-year lease agreement for administrative office space located in Bellaire, Texas. The term of the lease began on August 1, 2014 and was set to expire on July 31, 2019; however, in May 2019, we entered into an amendment to the lease agreement to extend the term of the lease for a period of five years, beginning on August 1, 2019 and ending on October 31, 2024.

In April 2016, the Company entered into a three-year lease agreement for lab space located in Bellaire, Texas that required Bio-Path to pay $2,500 per month over the term of the lease. The term of lease began on May 1, 2016 and was set to expire on April 30, 2019; however, in December 2018, we entered into an amendment to the lease agreement to extend the term for a period of three years, beginning on May 1, 2019 and ending on April 30, 2022. The amendment also amended the monthly rent from $2,500 per month to $2,575 per month over the term of the lease.

At the inception of an agreement, the Company determines if the agreement is a lease based on the unique facts and circumstances in each agreement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For agreements that contain a lease, we identify lease and non-lease components, determine the consideration in the contract, determine whether the lease is an operating or financing lease and recognize ROU assets and lease liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable so we use an incremental borrowing rate based on the information available at the lease commencement date, which represents an estimated rate that would be incurred to borrow over a similar term in a similar economic environment. The incremental borrowing rate utilized on our lease liabilities as of September 30, 2019 was 8.0%.

Our current leases include options to renew which can impact the lease term. The exercise of these options is at the Company's discretion and we do not include any of these options within the expected lease term as we are not reasonably certain we will exercise these options. Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis within our consolidated financial statements. Our leases are included in ROU assets, current portion of lease liabilities and noncurrent lease liabilities in our consolidated balance sheet as of September 30, 2019.

The following table summarizes our operating lease assets and liabilities as of September 30, 2019:

	ROU Assets and Liabilities (in thousands)
Assets:	
Operating lease assets	$ 388
Liabilities:	
Current portion of lease liabilities	79
Noncurrent lease liabilities	352
Total operating lease liabilities	$ 431

The following table summarizes our lease related costs for the nine months ended September 30, 2019:

	Lease Costs (in thousands)
Operating lease costs	$ 86
Variable lease costs	5
Total lease costs	$ 91

The Company made cash payments for its operating leases of $74,000 for the nine months ended September 30, 2019. We had $388,000 in non-cash investing and financing activities for the period ended September 30, 2019 related to the addition of ROU assets and corresponding operating lease liabilities recorded as part of the adoption of the new lease standard on January 1, 2019. Additionally, the Company recognized $31,000 of non-cash leasehold improvements for the nine months ended September 30, 2019.

The following table summarizes our expected minimum lease payments as of September 30, 2019:

As of September 30, 2019 (in thousands)	
2019	22
2020	115
2021	117
2022	98
2023	89
2024 and thereafter	76
Future minimum lease payments	517
Less: Interest	(86)
Present value of operating lease liabilities	$ 431

As of September 30, 2019, the weighted average remaining lease term was 4.7 years.

ASC 840 Disclosures

The following table summarizes our expected minimum lease payments as of December 31, 2018:

As of December 31, 2018 (in thousands)	
2019	82
2020	31
2021	31
2022	10
2023	-
2024 and thereafter	-
Future minimum lease payments	$ 154

The Company recognized $91,000 in rent expense for office and lab space for the nine months ended September 30, 2019.

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, 2018. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the matters discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2018, 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 treatment in over 70 patients, 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, we currently have three drug candidates in development to treat at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex" i je ber' sen), is in the efficacy portion of a Phase 2 clinical trial for acute myeloid leukemia (AML) in combination with low-dose cytarabine (LDAC) and in combination with decitabine. On March 6, 2019, we announced intended amendments to this Phase 2 clinical trial to, among other things, add prexigebersen in combination with decitabine for myelodysplastic syndrome and close prexigebersen in combination with LDAC. On August 26, 2019, we announced patient dosing in this amended Phase 2 clinical trial, as announced in March 2019. In addition, preclinical efficacy studies are underway for triple combination prexigebersen, decitabine and venetoclax in AML. Prexigebersen is also being studied in the safety portion of a Phase 2a clinical trial for chronic myeloid leukemia in combination with dasatinib. Prexigebersen was shown to enhance chemotherapy efficacy in preclinical solid tumor models, such as ovarian cancer, and we intend to file an Investigational New Drug (IND) application for prexigebersen in solid tumors in 2019.

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. We have filed an IND application with the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial of BP1002 in refractory/relapsed lymphoma and chronic lymphocytic leukemia patients once we receive approval from the FDA.

Our third drug candidate, Liposomal Stat3 ("BP1003"), targets the Stat3 protein and is currently in preclinical development 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 and significantly enhanced the efficacy of gemcitabine, a treatment for patients with advanced pancreatic cancer, in a pancreatic patient derived tumor model. Our lead indication for BP1003 is pancreatic cancer due to the severity of this disease and the lack of effective, life-extending treatments. We intend to have initiated IND enabling studies of BP1003 in 2019 and to file an IND application for a Phase 1 clinical trial of BP1003 for the treatment of solid tumors, including pancreatic cancer in 2020 and potentially, non-small cell lung cancer.

Our DNAbilize® technology-based products are available for out-licensing or partnering. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new nanoparticle antisense RNAi drug candidates. We have a new product identification template in place to define a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. As we expand, 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. On September 25, 2019, we announced that the United States Patent and Trademark Office issued a patent for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases.

We have certain intellectual property as the basis for our current drug products in clinical development, prexigebersen, BP1002 and BP1003. 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, 2019, we had an accumulated deficit of $54.0 million. Our net loss was $2.2 million and $3.1 million for the three months ended September 30, 2019 and 2018, respectively. Our net loss was $6.2 million and $6.7 million for the nine months ended September 30, 2019 and 2018, respectively. We expect to continue to incur significant operating losses, and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. To achieve profitability, we must enter into license or development agreements with third parties, or successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, debt financings and public or private equity offerings. We may seek to access the public or private equity markets whenever conditions are favorable; however, there can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Additionally, we may seek collaborations and license arrangements for our drug candidates. We currently have no lines of credit or other arranged access to debt financing.

Company History and Available Information

The Company was incorporated in May 2000 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with the Company, which at the time was traded over the counter and had no current operations. The prior name of the Company was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the Nasdaq Capital Market under the ticker symbol “BPTH.” Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law. Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357.

On February 8, 2018, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-10, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on February 9, 2018. In addition, on January 17, 2019, 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 January 18, 2019. All common stock share and per share amounts in this Quarterly Report on Form 10-Q have been adjusted to give effect to both the 1-for-10 reverse stock split and the 1-for-20 reverse stock split, retrospectively.

Recent Accounting Pronouncements

See Note 2 to the Unaudited Condensed Consolidated Financial Statements for a discussion of the impact of a new accounting standards update on the Company’s 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 in accordance with generally accepted accounting policies ("GAAP"). 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 trials 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; and
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates.

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, 2019 to the Three Months Ended September 30, 2018

Research and Development Expense. Our research and development expense for the three months ended September 30, 2019 was $1.4 million, a decrease of $1.0 million compared to the three months ended September 30, 2018. The decrease in research and development expense was primarily due to lower expenses in 2019 related to drug material releases for our Phase 2 clinical trials for prexigebersen in AML and CML. The following table sets forth our research and development expenses (in thousands):

	Three Months Ended September 30,	
	2019	2018
Research and development expense	$ 1,351	$ 2,320
Non-cash stock-based compensation expense	24	22
Total research and development expense	$ 1,375	$ 2,342

General and Administrative Expense. Our general and administrative expense for the three months ended September 30, 2019 was $0.9 million, an increase of $0.2 million compared to the three months ended September 30, 2018. The increase in general and administrative expense was primarily due to increased legal fees and insurance costs. The following table sets forth our general and administrative expenses (in thousands):

	Three Months Ended September 30,	
	2019	2018
General and administrative expense	$ 736	$ 609
Non-cash stock-based compensation expense	160	131
Total general and administrative expense	$ 896	$ 740

Net Operating Loss. Our net loss from operations for the three months ended September 30, 2019 was $2.3 million, a decrease of $0.8 million compared to the three months ended September 30, 2018.

Net Loss. Our net loss for the three months ended September 30, 2019 was $2.2 million, a decrease of $0.8 million compared to the three months ended September 30, 2018.

Net Loss per Share. Net loss per share, both basic and diluted, for the three months ended September 30, 2019 was $0.78 per share, compared to $5.38 per share for the three months ended September 30, 2018. 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, 2019 to the Nine Months Ended September 30, 2018

Research and Development Expense. Our research and development expense for the nine months ended September 30, 2019 was $3.3 million, a decrease of $0.8 million compared to the nine months ended September 30, 2018. The decrease in research and development expense was primarily due to lower expenses in 2019 related to drug material releases for our Phase 2 clinical trials for prexigebersen in AML and CML. The following table sets forth our research and development expenses (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Research and development expense	$ 3,221	$ 4,042
Non-cash stock-based compensation expense	75	59
Total research and development expense	$ 3,296	$ 4,101

General and Administrative Expense. Our general and administrative expense for the nine months ended September 30, 2019 was $3.0 million, an increase of $0.4 million compared to the nine months ended September 30, 2018. The increase in general and administrative expense was primarily due to increased legal fees, insurance costs and stock-based compensation expense. The following table sets forth our general and administrative expenses (in thousands):

	Nine Months Ended September 30,	
	2019	2018
General and administrative expense	$ 2,537	$ 2,222
Non-cash stock-based compensation expense	447	357
Total general and administrative expense	$ 2,984	$ 2,579

Net Operating Loss. Our net loss from operations for the nine months ended September 30, 2019 was $6.3 million, a decrease of $0.4 million compared to the nine months ended September 30, 2018.

Net Loss. Our net loss for the nine months ended September 30, 2019 was $6.2 million, a decrease of $0.5 million compared to the nine months ended September 30, 2018.

Net Loss per Share. Net loss per share, both basic and diluted, for the nine months ended September 30, 2019 was $2.51 per share, compared to $11.73 per share for the nine months ended September 30, 2018. 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 $15.4 million as of September 30, 2019, an increase of $14.4 million compared to December 31, 2018. We believe that our available cash at September 30, 2019 will be sufficient to meet obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months.

Cash Flows

Operating Activities. Net cash used in operating activities for the nine months ended September 30, 2019 was $6.1 million. Net cash used in operating activities consisted primarily of the net loss for the period of $6.2 million, excluding non-cash stock-based compensation expense of $0.5 million and depreciation and amortization expenses of $0.2 million, an increase in current assets of $0.4 million and a decrease in current liabilities of $0.2 million.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2019 was $20.5 million. Net cash provided by financing activities consisted primarily of net proceeds of $19.4 million from the 2019 Underwritten Offering, the January 2019 Registered Direct Offering and January 2019 Private Placement and the March 2019 Registered Direct Offering, each as described below, as well as net proceeds of $1.1 million from the exercise of warrants to purchase shares of our common stock.

2019 Shelf Registration Statement

On May 16, 2019, we filed a shelf registration on Form S-3 with the SEC, which was declared effective by the SEC on June 5, 2019 (File No. 333-231537) (the "2019 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 January 9, 2017 (File No. 333-215205) (the "2017 Shelf Registration Statement") was deemed terminated pursuant to Rule 415(a)(6) under the Securities Act. The 2019 Shelf Registration Statement was filed to register the offering, issuance and sale of (i) up to $125.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units, including offers and sales of our common stock under the Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") described below and (ii) up to 5,149 shares of our common stock pursuant to the exercise of warrants that were issued in a registered direct offering in 2016. 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.

"At the Market" Offering

On June 24, 2015, we entered into the Sales Agreement with Cantor Fitzgerald, as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock. Sales of shares of common stock under the Sales Agreement will be made pursuant to the 2019 Shelf Registration Statement and a related prospectus filed with the SEC on June 6, 2019, for an aggregate offering price of up to $25.0 million. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act. We will pay Cantor Fitzgerald a commission of 3.4% of the aggregate gross proceeds from each sale of shares under the Sales Agreement and have agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. We have also agreed to reimburse Cantor Fitzgerald for certain specified expenses. The Sales Agreement may be terminated by either Cantor Fitzgerald or the Company upon ten days' notice. We are subject to certain restrictions on our ability to offer and sell shares of our common stock under the Sales Agreement. To date, we have not offered or sold any shares of common stock under the Sales Agreement.

2018 Registered Direct Offering and 2018 Private Placement

On September 20, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 98,454 shares of our common stock and pre-funded warrants to purchase up to 14,624 shares of our common stock for gross proceeds of approximately $1.5 million under the 2017 Shelf Registration Statement (the "2018 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 113,077 shares of our common stock (the "2018 Private Placement"). Additionally, we issued warrants to purchase up to 6,785 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the 2018 Registered Direct Offering and the 2018 Private Placement. The 2018 Registered Direct Offering and the 2018 Private Placement closed on September 25, 2018. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $1.2 million.

2019 Underwritten Offering

On January 14, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC relating to an underwritten public offering of 429,616 shares of our common stock for gross proceeds of approximately $1.1 million under the 2017 Shelf Registration Statement. The offering price to the public in the 2019 Underwritten Offering was $2.60 per share, and H.C. Wainwright & Co., LLC agreed to purchase the shares in the 2019 Underwritten Offering from the Company pursuant to the underwriting agreement at a price of $2.418 per share. Additionally, we issued warrants to purchase up to 25,777 shares of our common stock in a private placement to the H.C. Wainwright & Co., LLC as compensation for its services as underwriter in connection with the 2019 Underwritten Offering. The 2019 Underwritten Offering closed on January 17, 2019. The net proceeds to the Company from the 2019 Underwritten Offering, after deducting the underwriting discounts and commissions and expenses and the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the underwriter warrants, were approximately $0.9 million.

January 2019 Registered Direct Offering and January 2019 Private Placement

On January 18, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 648,233 shares of our common stock for gross proceeds of approximately $1.7 million under the 2017 Shelf Registration Statement. In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 324,117 shares of our common stock. Additionally, we issued warrants to purchase up to 38,894 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the 2019 Registered Direct Offering and the January 2019 Private Placement. The January 2019 Registered Direct Offering and the January 2019 Private Placement closed on January 23, 2019. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $1.5 million.

March 2019 Registered Direct Offering

On March 12, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 712,910 shares of our common stock for gross proceeds of approximately $18.5 million under the 2017 Shelf Registration Statement. Additionally, we issued warrants to purchase up to 42,775 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the March 2019 Registered Direct Offering. The March 2019 Registered Direct Offering closed on March 14, 2019. The net proceeds to us from the offering, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $17.0 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 and BP1003. 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, 2018. For more information, see Note 1 to the Unaudited Condensed Consolidated Financial Statements included herein.

Off-Balance Sheet Arrangements

As of September 30, 2019, we did not have any material off-balance sheet arrangements.

Critical Accounting Policies

The preparation of financial statements in conformity with GAAP in the United States has required the management of the Company 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. Except as disclosed below, 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, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. Effective January 1, 2019 we adopted ASU No. 2016-02, *Leases*. Management has determined that the Company's ROU asset and lease liability did not have a significant impact on the Company's consolidated financial statements. See Note 2, *Recent Accounting Pronouncements*, and Note 10, *Leases,* of the Notes to Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional details regarding the impact of the adoption of this standard.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Our management, including our Chief Executive Officer (who is also our Chief Financial Officer), has reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Following this review and evaluation, our management determined that as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not 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.

As previously disclosed under "Item 9A. Controls and Procedures" to Part II of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2018, our management identified a material weakness in our internal control over financial reporting relating to the design of our controls to prevent a misstatement resulting from the information and communication between our clinical and finance personnel as it relates to an input for our clinical trial expense accrual. Our management has been committed to the planning and implementation of remediation efforts to address the material weakness in our internal control over financial reporting. We designed and implemented processes and internal controls to improve communication between our clinical and finance personnel in addition to using a report to substantiate the input used in our clinical trial expense accrual. These remediation efforts were intended both to address the identified material weakness and to enhance our overall financial control environment. Our management is in the process of evaluating the controls to verify they remediate the material weakness, which is expected to be resolved by year end.

Changes in Internal Control over Financial Reporting

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

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

There were no material changes from the risk factors previously disclosed under "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2018.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.2	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2018).
3.3	First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 7, 2017).
3.4	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
31*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
32**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* 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, 2019

BIO-PATH HOLDINGS, INC.

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

Exhibit 31

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER

I, Peter H. Nielsen, certify that:

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

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our 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, 2019

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

Exhibit 32

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

In connection with the Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc. (the "Company") for the quarter ended September 30, 2019 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, 2019

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