BIO-PATH HOLDINGS INC
Form 10-Q
August 14, 2018

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

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)

Registrant's telephone no., including area code: (832) 742-1357

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x
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 x

At August 1, 2018, the Company had 11,340,756 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 va 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, 2017 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, 2017 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.

TABLE OF CONTENTS

Part I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)
(Unaudited)

	As of June 30, 2018	As of December 31, 2017
Assets		
Current assets		
Cash	$ 2,578	$ 5,965
Prepaid drug product for testing	1,332	1,117
Other current assets	604	353
Total current assets	4,514	7,435
Fixed assets		
Furniture, fixtures & equipment	1,001	984
Less accumulated depreciation	(462)	(330)
	539	654
Other assets		
Technology licenses	2,500	2,500
Less accumulated amortization	(1,811)	(1,731)
	689	769
Total Assets	$ 5,742	$ 8,858
Liabilities & Shareholders' Equity		
Current liabilities		
Accounts payable	$ 137	$ 52

Accrued expenses	868	739
Total current liabilities	1,005	791
Total Liabilities	1,005	791
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; 11,341 and 11,339 shares issued and outstanding, respectively	11	11
Additional paid in capital	47,476	47,213
Accumulated deficit	(42,750)	(39,157)
Total shareholders' equity	4,737	8,067
Total Liabilities & Shareholders' Equity	$ 5,742	$ 8,858

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 827	$ 1,480	$ 1,759	$ 2,506
General and administrative	852	845	1,839	1,815
Total operating expenses	1,679	2,325	3,598	4,321
Net operating loss	$ (1,679)	$ (2,325)	$ (3,598)	$ (4,321)
Other income (loss)				
Change in fair value of warrant liability	-	778	-	2,374
Loss on extinguishment of warrant liability	-	(440)	-	(440)
Interest income	2	2	5	5
Total other income	2	340	5	1,939
Net loss	$ (1,677)	$ (1,985)	$ (3,593)	$ (2,382)
Deemed dividend related to warrant conversion	-	(1,038)	-	(1,038)
Net loss attributable to common stockholders	$ (1,677)	$ (3,023)	$ (3,593)	$ (3,420)
Net loss per share, basic and diluted	$ (0.15)	$ (0.31)	$ (0.32)	$ (0.35)
Basic and diluted weighted average number of common shares outstanding	11,341	9,859	11,341	9,712

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flow from operating activities		
Net loss	$(3,593)	$(2,382)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization	80	80
Depreciation	132	108
Stock-based compensation	263	507
Change in fair value of warrant liability	-	(2,374)
Loss on extinguishment of warrant liability	-	440
(Increase) decrease in assets		
Prepaid drug product for testing	(215)	(216)
Other current assets	(251)	(109)
Increase (decrease) in liabilities		
Accounts payable and accrued expenses	214	(257)
Net cash used in operating activities	(3,370)	(4,203)
Cash flow from investing activities		
Purchases of furniture, fixtures & equipment	(17)	(538)
Net cash used in investing activities	(17)	(538)
Cash flow from financing activities		
Net proceeds from exercise of warrants	-	1,548
Net cash provided by financing activities	-	1,548
Net decrease in cash	(3,387)	(3,193)
Cash, beginning of period	5,965	9,375

Cash, end of period	$2,578	$6,182
Supplemental disclosure of non-cash activities		
Non-cash financing activities		
Warrants transferred to equity upon modification	$-	$797
Conversion of warrant liability to equity	$-	$175
Offering expenses included in accrued expenses	$-	$30

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

Notes to the Unaudited Condensed Consolidated Financial Statements
for the Period Ended June 30, 2018

Unless the context requires otherwise, references in these Notes to the Unaudited 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, 2017. The results of operations for the period ended June 30, 2018, 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 of antisense drug substances 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 *in vivo*, incorporated inside of a neutral charge lipid bilayer. 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 targeted 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 a total of five different 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). On April 3, 2018, we announced that interim data from the efficacy portion of the Phase 2 clinical trial for AML demonstrated that the combination therapy continues to be well-tolerated and has shown early anti-leukemic activity in nearly 50% of evaluable AML patients, including four patients with complete remission and four with stable disease to date in this study. In addition, a Phase 2a clinical trial of prexigebersen, which is the safety segment of a Phase 2 clinical trial, for blast phase and accelerated phase chronic myelogenous leukemia (CML) is open for enrollment. Prexigebersen is also in preclinical studies for solid tumors, including breast cancer and ovarian cancer.

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 are currently preparing an Investigational New Drug (IND) application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase 1 clinical trial of BP1002 in refractory or relapsed lymphoma patients once we receive approval from the U.S. Food and Drug Administration (FDA).

Our third drug candidate, Liposomal Stat3 (“BP1003”), targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. We intend to initiate IND enabling studies of BP1003 in 2018.

Bio-Path Subsidiary was founded in May 2007 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. 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.

In June 2016, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with certain healthcare focused institutional investors pursuant to which the Company agreed to sell an aggregate of 588,235 shares of the Company’s common stock and warrants (the “2016 Registered Warrants”) to purchase up to 294,118 shares of the Company’s common stock for gross proceeds of approximately $10.0 million (the “2016 Registered Direct Offering”). The 2016 Registered Direct Offering closed on July 5, 2016. The Company also issued warrants (the “2016 Placement Warrants,” and together with the 2016 Registered Warrants, the “2016 Warrants”) to purchase up to 25,000 shares of the Company’s common stock in a private placement to H.C. Wainwright & Co., LLC and its designees as compensation for its services as a placement agent in connection with the 2016 Registered Director Offering. The net proceeds to the Company from the 2016 Registered Direct Offering, after deducting the placement agent’s fees and expenses and the Company’s offering expenses, and excluding the proceeds from the exercise of the warrants issued in the offering, were approximately $9.3 million. These proceeds were partially offset by additional financing costs incurred of $0.3 million.

On May 21, 2017, the Company entered into Warrant Exercise Agreements (the “Exercise Agreements”) with certain holders (the “Exercising Holders”) of the 2016 Warrants and warrants to purchase shares of common stock that we issued in January 2014 (the “2014 Warrants,” and together with the 2016 Warrants, the “Original Warrants”). The Exercising Holders owned, in the aggregate, Original Warrants exercisable for 441,176 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their Original Warrants with respect to 430,000 shares of our common stock underlying such Original

Warrants for a reduced exercise price equal to $3.80 per share (the “Reduced Exercise Price”). The Exercising Holders also subsequently exercised their Original Warrants for the remaining 11,176 shares of our common stock underlying such Original Warrants for the Reduced Exercise Price. In connection with the execution of the Exercise Agreements, we issued to each Exercising Holder a new warrant (each, a “New Warrant”) to purchase shares of our common stock equal to the number of shares of our common stock received by such Exercising Holder upon exercise of such Exercising Holder’s Original Warrants. The terms of the New Warrants are substantially similar to the terms of the Original Warrants, except that the New Warrants (i) became exercisable immediately upon issuance for a period of five years from the closing date of the Exercise Agreements; (ii) have an exercise price equal to $6.00 per share and (iii) included revised language substantially similar to the language in the Warrant Amendments described below regarding fundamental transactions and net cash settlement. As noted below, this modified language results in the New Warrants qualifying for equity treatment on the Company’s Consolidated Balance Sheet. The net proceeds to the Company from the exercise of the New Warrants by the Exercising Holders, after deducting financial advisory fees and expenses and our offering expenses, were approximately $1.5 million.

On June 13, 2017, the Company entered into amendments (the "Warrant Amendments") with holders (the "Holders") of the remaining 2016 Warrants, which amended the terms of their 2016 Warrants exercisable for 127,941 shares of our common stock. The Warrant Amendments provide that (i) the Holders' right to require the Company to purchase the outstanding warrants upon the occurrence of certain fundamental transactions will not apply if the fundamental transaction is a result of a transaction that has not been approved by the Board of Directors and (ii) in the event the Company does not have an effective registration statement registering the issuance of the underlying shares of our common stock to the Holders, there is no circumstance that would require the Company to net cash settle the outstanding warrants. As such, the changes made in the Warrant Amendments allow for equity treatment of the remaining 2016 Warrants. As a result of the Exercise Agreements and the Warrant Amendments, the Company's Warrant Liability was extinguished, allowing the New Warrants and the remaining 2016 Warrants, as amended, to be treated as equity for all filings beginning with the quarter ended June 30, 2017.

The Exercise Agreements for the 2014 Warrants resulted in the holders receiving $1.0 million in incremental value over the value of the warrants at the exchange date. This incremental value was recorded as a deemed dividend in additional paid-in capital due to the absence of retained earnings and increased the net loss available to common stockholders on the Consolidated Statements of Operations. The Exercise Agreements for the 2016 Warrants resulted in warrants with a fair value of $0.4 million being extinguished and resulted in the recognition of a loss on extinguishment of warrants of $0.4 million. Additionally, the Warrant Amendments resulted in the reclassification of the remaining 2016 Warrants with a fair value of $0.2 million from liability presentation to equity treatment on the Consolidated Balance Sheet.

On November 3, 2017, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell an aggregate of 1,333,333 shares of our common stock and warrants to purchase up to 666,667 shares of our common stock for gross proceeds of approximately $4.0 million under an effective shelf registration statement on Form S-3 (the "2017 Registered Direct Offering"). We also issued warrants to purchase up to 16,000 shares of common stock in a private placement to Roth Capital Partners, LLC as compensation for its services as a placement agent in connection with the 2017 Registered Direct Offering. The 2017 Registered Direct Offering closed on November 6, 2017. The net proceeds to the Company from the 2017 Registered Direct 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 $3.6 million.

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. 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-10 reverse stock split.

As of June 30, 2018, the Company had $2.6 million in cash on hand, compared to $6.0 million as of December 31, 2017. Management has completed its analysis of the Company's cash needs and determined that it does not have enough cash on hand to meet obligations and fund operations for the next 12 months from the report date included

herein. We expect to finance our foreseeable cash requirements through cash on hand, debt financings and public or private equity offerings. Additionally, we may seek collaborations and license arrangements for our drug candidates. We may seek to access the public or private equity markets whenever conditions are favorable. We currently have no lines of credit or other arranged access to debt financing. If the Company is unable to obtain funding due to unfavorable terms or market conditions, management has determined that it can reduce spending on its day-to-day operations, sell laboratory assets and temporarily delay planned activities if needed. However, these conditions raise substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon obtaining funding within the next 12 months to meet its planned obligations and pay its liabilities.

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. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers.* The new standard provides comprehensive guidance for recognizing revenue as goods or services are delivered to the customer in an amount that is expected to be earned from those same goods or services. ASU 2014-09 was scheduled to be effective for annual reporting periods beginning after December 15, 2016, and early adoption was not permitted. In August 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers: Deferral of Effective Date", which defers the effective date of ASU 2014-09 by one year. ASU 2014-19 is now effective for annual periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is permitted only for annual periods beginning after December 15, 2016, including interim periods within that reporting period and allows for adoption using a full retrospective method, or a modified retrospective method. The Company adopted the standard on January 1, 2018 using the modified retrospective method of adoption and determined that it did not have a material effect on our consolidated financial statements as the Company currently does not have significant contracts with customers.

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. Management is currently evaluating the impact of future adoption of the new standard on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation: Scope of Modification Accounting*. The new standard requires an entity to apply modification accounting provisions if the value, vesting conditions or classification of the award changes. The new guidance must be applied on a prospective basis and is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. The Company adopted the standard on January 1, 2018 on a prospective basis and determined that it did not have a material effect on our consolidated financial statements

In June 2018, the FASB issued ASU No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* The new standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees. Equity-classified share-based payments issued to nonemployees will be measured on the grant date instead of being remeasured through the performance completion date as required under the current guidance. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company early adopted this standard effective June 30, 2018 and notes the adoption did not have a significant impact on the Company's consolidated financial statements.

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

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 made payments to its contract drug manufacturing and raw material suppliers in late 2016 and through 2017 totaling $1.1 million pursuant to drug supply contracts for the manufacture and delivery of prexigebersen for testing in Phase 2 clinical trials and Bcl-2 in preparation for a Phase 1 clinical trial. This amount was carried on the Balance Sheet as of December 31, 2017 at cost as Prepaid Drug Product for Testing. The Company incurred additional installment costs of $0.2 million during the first six months of 2018 resulting in advanced payments totaling $1.3 million, which are carried on the Balance Sheet as of June 30, 2018 as Prepaid Drug Product for Testing (See Note 9).

4. Other Current Assets

As of June 30, 2018, Other Current Assets included prepaid expenses of $0.6 million, comprised primarily of prepayments made to the Company’s clinical research organization for our clinical trial for prexigebersen in CML of $0.4 million and prepaid insurance of $0.2 million. As of December 31, 2017, Other Current Assets included prepaid expenses of $0.4 million.

5. Accounts Payable

As of June 30, 2018, Current Liabilities included accounts payable of $0.1 million, comprised primarily of amounts owed for legal fees and external research expenses. As of December 31, 2017, Current Liabilities included accounts payable of $0.1 million.

6. Accrued Expenses

As of June 30, 2018, Current Liabilities included accrued expenses of $0.9 million, comprised primarily of accrued clinical and preclinical expenses of $0.5 million, employee vacation and bonus expenses of $0.2 million, an annual license maintenance fee of $0.1 million and other accrued expenses of $0.1 million. As of December 31, 2017, Current Liabilities included accrued expense of $0.7 million, comprised primarily of accrued clinical and preclinical expenses of $0.4 million, employee vacation and bonus expenses of $0.1 million, an annual license maintenance fee of $0.1 million and other accrued expenses of $0.1 million.

7. Stockholders’ Equity

Stockholders' Equity totaled $4.7 million as of June 30, 2018 compared to $8.1 million as of December 31, 2017. There were 11,340,756 shares of common stock issued and outstanding as of June 30, 2018. There were no preferred shares outstanding as of June 30, 2018.

8. Stock-Based Compensation

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, 2017, the total number of shares reserved and available for grant and issuance pursuant to the 2017 Plan was 1,200,000 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 was $0.1 million and $0.3 million for the three months ended June 30, 2018 and June 30, 2017, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for both the three months ended June 30, 2018 and June 30, 2017 was $0.1 million. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended June 30, 2018 and June 30, 2017 was $17,000 and $0.1 million, respectively.

Stock-based compensation expense was $0.3 million and $0.5 million for the six months ended June 30, 2018 and June 30, 2017, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the six months ended June 30, 2018 and June 30, 2017 was $0.2 million and $0.3 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the six months ended June 30, 2018 and June 30, 2017 was $37,000 and $0.2 million, respectively.

The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock options granted, with the following weighted-average assumptions for options granted in the six months ended June 30, 2018 and 2017:

	2018	2017
Risk-free interest rate	2.69%	2.06%
Expected volatility	90 %	99 %
Expected term in years	6.1	6.1
Dividend yield	- %	- %

The following summary represents option activity under the Company's stock-based compensation plan for the six months ended June 30, 2018:

	Options (in thousands)	Weighted-Average Exercise Price
Outstanding at December 31, 2017	642	$ 11.60
Granted	390	1.73
Cancelled	(4)	11.88
Expired	(39)	10.61
Outstanding at June 30, 2018	989	7.76
Exercisable at June 30, 2018	546	$ 10.98

As of June 30, 2018, 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 June 30, 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2018. This amount changes based on the fair market value of the Company’s stock.

As of June 30, 2018, unamortized stock-based compensation expense for all outstanding options was $1.0 million, which is expected to be recognized over a weighted average vesting period of 2.3 years.

9. Commitments and Contingencies

Technology License – The Company has negotiated exclusive licenses from MD Anderson to clinically develop liposomal antisense and siRNA drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense and an annual license maintenance fee. The annual license maintenance fee attributable to the License Agreement totaling $0.1 million was included in Current Liabilities as of June 30, 2018 and December 31, 2017.

Operating Lease – In April 2014, the Company entered into a five-year lease agreement for office space, which it occupied as of August 2014. The remaining lease payments due under this lease as of June 30, 2018 are $0.1 million.

In April 2016, the Company entered into a three-year lease agreement for lab space located in Bellaire, Texas. The term of lease began on May 1, 2016 and terminates on April 30, 2019 and will require Bio-Path to pay $2,500 per month over the term of the lease. The remaining lease payments due under this lease as of June 30, 2018 are $25,000.

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 $1.3 million and are carried on the balance sheet as of June 30, 2018 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 June 30, 2018, comprised of $0.9 million to the manufacturer of prexigebersen and BP1002, $0.4 million for manufacture of our drug substance and $0.1 million for manufacturing development. We expect to incur $0.8 million of these commitments over the next 12 months.

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

When you read this Item of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of the fiscal year ended December 31, 2017. 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, 2017 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 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 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 a total of five different 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). On April 3, 2018, we announced that interim data from the efficacy portion of the Phase 2 clinical trial for AML demonstrated that the combination therapy continues to be well-tolerated and has shown early anti-leukemic activity in nearly 50% of evaluable AML patients, including four patients with complete remission and four with stable disease to date in this study. In addition, a Phase 2a clinical trial of prexigebersen, which is the safety segment of a Phase 2 clinical trial, for blast phase and accelerated phase chronic myelogenous leukemia is open for enrollment. Prexigebersen is also in preclinical studies for solid tumors, including breast cancer and ovarian cancer.

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 are currently preparing an Investigational New Drug (IND) application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase 1 clinical trial of BP1002 in refractory or relapsed lymphoma patients once we receive approval from the U.S. Food and Drug Administration (FDA).

Our third drug candidate, Liposomal Stat3 (“BP1003”), targets the Stat3 protein and is currently in preclinical development in a pancreatic patient-derived tumor model. Previous preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. 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 initiate IND enabling studies of BP1003 in 2018.

Our DNAbilize® technology is available for out-licensing. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. A significant amount of capital is expected to be allocated to in-license promising protein targets that can be developed as new liposomal antisense drug candidates. As we expand, we will look at indications where a systemic delivery is needed and antisense can be used to slow, reverse or cure a disease, either alone or in combination with another drug. On July 19, 2017, we announced that the United States Patent and Trademark Office (“USPTO”) issued a notice of allowance 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 and BP1002. We also currently maintain an exclusive license agreement (the "License Agreement") with The University of Texas, MD Anderson Cancer Center ("MD Anderson"), under which we license from MD Anderson certain technology relating to the original delivery technology platform. 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 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 manufacture of neutral charged DNA-liposome complexes.

On April 3, 2018, we announced that interim data from our Phase 2 study of prexigebersen in combination with LDAC ("BP1001-201") for the treatment of AML demonstrated that the combination therapy continues to be well-tolerated and has shown early anti-leukemic activity in nearly 50% of evaluable AML patients, including four patients with complete remission and four with stable disease to date in this study. The open-label Phase 2 study is evaluating the efficacy and safety of prexigebersen in conjunction with LDAC. The primary objective of the study is to determine whether the combination of prexigebersen and LDAC provides greater efficacy than what would be expected with LDAC alone in this de novo patient population. The study had a pre-determined decision point at 19 evaluable patients in which the study would be terminated if less than five patients responded and the study would be expanded to 54 patients if five or more patients responded.

The interim analysis was performed on 17 evaluable patients instead of 19, since criteria to move to the next steps in the study had been met. Of the 17 evaluable patients, there were four patients who achieved complete responses, one patient who achieved a morphologic leukemia free state, two patients who had significantly reduced bone marrow blasts and four patients with stable disease. In total, 47% of the evaluable patients showed some form of response, including stable disease, to the combination treatment. The average age of patients in the study was 73.5 years old.

Based on the recommendations of the principal investigators of the study, we are amending the protocol to change the dosing schedule to that used in the Phase 1b study in relapsed and refractory AML patients in which a higher dose of prexigebersen was administered prior to LDAC treatment starting at day 10 versus LDAC treatment starting on day four as was the case in the BP1001-201 study to date. In addition, the investigators endorse the inclusion of a decitabine cohort based on relatively new and positive data with this compound.

As of June 30, 2018, we had an accumulated deficit of $42.8 million. Our net loss was $1.7 million and $2.0 million for the three months ended June 30, 2018 and 2017, respectively. Our net loss was $3.6 million and $2.4 million for the six months ended June 30, 2018 and 2017, 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

We were originally incorporated in May 2000 as a Utah corporation under the name Ogden Golf Co. Corporation, but terminated our retail golf store operations in December 2006. In February 2008, we completed a reverse merger with Bio-Path Subsidiary. The name of Ogden Golf Co. Corporation 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. 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-10 reverse stock split.

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;

- license fees, including maintenance fees and patent expense paid to MD Anderson in connection with the License Agreement; 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 June 30, 2018 to the Three Months Ended June 30, 2017

Research and Development Expense. Our research and development expense for the three months ended June 30, 2018 was $0.8 million, a decrease of $0.7 million compared to the three months ended June 30, 2017. The decrease in research and development expense was primarily due to decreased clinical, manufacturing and salaries and benefits expenses. The following table sets forth our research and development expenses (in thousands):

	Three Months Ended June 30,	
	2018	**2017**
Research and development expense	$810	$1,351
Non-cash stock-based compensation expense	17	129
Total research and development expense	$827	$1,480

General and Administrative Expense. Our general and administrative expense for the three months ended June 30, 2018 was $0.9 million, compared to $0.8 million for the three months ended June 30, 2017. The following table sets forth our general and administrative expenses (in thousands):

	Three Months Ended June 30,	
	2018	**2017**
General and administrative expense	$730	$716
Non-cash stock-based compensation expense	122	129
Total general and administrative expense	$852	$845

Net Operating Loss. Our net loss from operations was $1.7 million for the three months ended June 30, 2018, a decrease of $0.3 million compared to the three months ended June 30, 2017.

Change in Fair Value of Warrant Liability. The Company did not have a warrant liability for the three months ended June 30, 2018. The change in fair value of the warrant liability for the three months ended June 30, 2017 resulted in non-cash income of $0.8 million.

Loss on Extinguishment of Warrant Liability. The Company did not have a warrant liability for the three months ended June 30, 2018. The loss on extinguishment of the warranty liability for the three months ended June 30, 2017 resulted in a non-cash loss of $0.4 million.

Net Loss. Our net loss for the three months ended June 30, 2018 was $1.7 million, a decrease of $0.3 million compared to the three months ended June 30, 2017.

Deemed Dividend Related to Warrant Conversion. The Company did not have a deemed divided related to warrant conversion for the three months ended June 30, 2018. The deemed dividend related to warrant conversion was $1.0 million for the three months ended June 30, 2017.

Net Loss Attributable to Common Stockholders. Our net loss attributable to common stockholders for the three months ended June 30, 2018 was $1.7 million, a decrease of $1.3 million compared to the three months ended June 30, 2017.

Net Loss per Share. Net loss per share, both basic and diluted, was $0.15 per share for the three months ended June 30, 2018, compared to $0.31 per share for the three months ended June 30, 2017. Net loss per share is calculated using the weighted average number of shares of common stock outstanding during the applicable periods and excludes stock options and warrants because they are antidilutive.

Comparisons of the Six Months Ended June 30, 2018 to the Six Months Ended June 30, 2017

Research and Development Expense. Our research and development expense for the six months ended June 30, 2018 was $1.8 million, a decrease of $0.7 million compared to the six months ended June 30, 2017. The decrease in research and development expense was primarily due to decreased salaries and benefits expense. The following table sets forth our research and development expenses (in thousands):

	Six Months Ended	
	June 30,	
	2018	**2017**
Research and development expense	$1722	$2,256
Non-cash stock-based compensation expense	37	250
Total research and development expense	$1,759	$2,506

General and Administrative Expense. Our general and administrative expense for both the six months ended June 30, 2018 and June 30, 2017 was $1.8 million. The following table sets forth our general and administrative expenses (in thousands):

	Six Months Ended
	June 30,

	2018	2017
General and administrative expense	$1,613	$1,558
Non-cash stock-based compensation expense	226	257
Total general and administrative expense	$1,839	$1,815

Net Operating Loss. Our net loss from operations was $3.6 million for the six months ended June 30, 2018, a decrease of $0.7 million compared to the six months ended June 30, 2017.

Change in Fair Value of Warrant Liability. The Company did not have a warrant liability for the six months ended June 30, 2018. The change in fair value of the warrant liability for the six months ended June 30, 2017 resulted in non-cash income of $2.4 million.

Loss on Extinguishment of Warrant Liability. The Company did not have a warrant liability for the six months ended June 30, 2018. The loss on extinguishment of the warranty liability for the six months ended June 30, 2017 resulted in a non-cash loss of $0.4 million.

Net Loss. Our net loss for the six months ended June 30, 2018 was $3.6 million, an increase of $1.2 million compared to the six months ended June 30, 2017.

Deemed Dividend Related to Warrant Conversion. The Company did not have a deemed divided related to warrant conversion for the six months ended June 30, 2018. The deemed dividend related to warrant conversion was $1.0 million for the six months ended June 30, 2017.

Net Loss Attributable to Common Stockholders. Our net loss attributable to common stockholders for the six months ended June 30, 2018 was $3.6 million, an increase of $0.2 million compared to the six months ended June 30, 2017.

Net Loss per Share. Net loss per share, both basic and diluted, was $0.32 per share for the six months ended June 30, 2018 compared to $0.35 per share for the six months ended June 30, 2017. 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 $2.6 million as of June 30, 2018, a decrease of $3.4 million compared to December 31, 2017. We do not believe that our available cash at June 30, 2018 will be sufficient to fund our liquidity and capital expenditure requirements for the next 12 months. The Company’s ability to continue as a going concern is dependent upon obtaining funding through one or more sources as described above within the next 12 months to meet its planned obligations and pay its liabilities.

Cash Flows

Operating Activities. Net cash used in operating activities for the six months ended June 30, 2018 was $3.4 million. Net cash used in operating activities consisted primarily of the net loss for the period of $3.6 million and an increase in prepaid expenses and other current assets of $0.5 million. Our net cash used in operating activities is partially offset by stock-based compensation expense of $0.3 million, an increase in current liabilities of $0.2 million and amortization and depreciation expenses of $0.2 million.

Investing Activities. Net cash used in investing activities for the six months ended June 30, 2018 consisted of capital expenditures totaling $17,000, which were related to research and development equipment purchases.

2017 Shelf Registration Statement

On December 20, 2016, we filed a shelf registration on Form S-3 with the SEC, which was declared effective by the SEC on January 9, 2017 (File No. 333-215205) (the "2017 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 13, 2014 (File No. 333-192102) (the "2014 Shelf Registration Statement"), was deemed terminated pursuant to Rule 415(a)(6) under the Securities Act. The 2017 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 Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") described below and (ii) up to 544,178 shares of our common stock pursuant to the exercise of warrants that were issued in a registered direct offering in 2014 and a registered direct offering in 2016. Because our public float is less than $75 million, our ability to offer and sell any securities under the 2017 Shelf Registration Statement is currently limited pursuant to Instruction I.B.6 to Form S-3. For so long as the Company's public float is less than $75 million, the aggregate market value of securities sold by the Company under the 2017 Shelf Registration Statement pursuant to Instruction I.B.6 to Form S-3 during any 12 consecutive months may not exceed one-third of the Company's 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.

"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 2017 Shelf Registration Statement and a related prospectus filed with the SEC on January 10, 2017, 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.

Warrant Exercises

On May 21, 2017, the Company entered into Warrant Exercise Agreements (the "Exercise Agreements") with certain holders (the "Exercising Holders") of warrants to purchase shares of common stock that we issued in June 2016 (the "2016 Warrants") and warrants to purchase shares of common stock that we issued in January 2014 (the "2014 Warrants," and together with the 2016 Warrants, the "Original Warrants"). The Exercising Holders owned, in the aggregate, Original Warrants exercisable for 441,176 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their Original Warrants with respect to 430,000 shares of our common stock underlying such Original Warrants for a reduced exercise price equal to $3.80 per share (the "Reduced Exercise Price"). The Exercising Holders also subsequently exercised their Original Warrants for the remaining 11,176 shares of our common stock underlying such Original Warrants for the Reduced Exercise Price. In connection with the execution of the Exercise Agreements, we issued to each Exercising Holder a new warrant (each, a "New Warrant") to purchase shares of our common stock equal to the number of shares of our common stock received by such Exercising Holder upon exercise of such Exercising Holder's Original Warrants. The terms of the New Warrants are substantially similar to the terms of the Original Warrants, except that the New Warrants (i) became exercisable immediately upon issuance for a period of five years from the closing date of the Exercise Agreements; (ii) have an exercise price equal to $6.00 per share and (iii) included revised language providing that the holders' right to require the Company to purchase the outstanding New Warrants upon the occurrence of certain fundamental transactions will not apply if the fundamental transaction is a result of a transaction that has not been approved by the Board and that in the event the Company does not have an effective registration statement registering the issuance of the underlying shares of our common stock to the holders, there is no circumstance that would require the Company to net cash settle the outstanding New Warrants. The net proceeds to the Company from the exercise of the New Warrants by the Exercising Holders, after deducting financial advisory fees and expenses and our offering expenses, were approximately $1.5 million.

2017 Registered Direct Offering

On November 3, 2017, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell an aggregate of 1,333,333 shares of our common stock and warrants to purchase up to 666,667 shares of our common stock for gross proceeds of approximately $4.0 million under the 2017 Shelf Registration Statement (the "2017 Registered Direct Offering"). We also issued warrants to purchase up to 16,000 shares of common stock in a private placement to Roth Capital Partners, LLC as compensation for its services as a placement agent in connection with the 2017 Registered Direct Offering. The 2017 Registered Direct Offering closed on November 6, 2017. The net proceeds to the Company from the 2017 Registered Direct 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 $3.6 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, 2017. For more information, see Note 1 to the Unaudited Condensed Consolidated Financial Statements included herein.

Off-Balance Sheet Arrangements

As of June 30, 2018, 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. Our significant accounting policies are discussed in Note 2 to our Consolidated Financial Statements included in our Annual Report on Form 10-K as of the year ended December 31, 2017.

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 are 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.

21

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, 2017.

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).
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.

SIGNATURE

In accordance with the requirements of the Exchange Act, the Company has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: August 14, 2018 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)

23

EXHIBIT INDEX

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).
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.