

BIO-PATH HOLDINGS INC
Form S-1
December 27, 2018

As filed with the Securities and Exchange Commission on December 27, 2018
Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

87-0652870

(I.R.S. Employer

Identification Number)

4710 Bellaire Boulevard, Suite 210

Bellaire, Texas 77401

(832) 742-1357

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Peter H. Nielsen

President and Chief Executive Officer

4710 Bellaire Boulevard, Suite 210

Bellaire, Texas 77401

(832) 742-1357

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies To:

William R. Rohrlich, II

Winstead PC

**600 Travis Street
Suite 5200**

Houston, Texas 77002

Tel. (281) 681-5912

Fax (281) 681-5901

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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 x 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 7(a)(2)(B) of the Securities Act. "

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Aggregate Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock, par value \$0.001 per share, issuable upon exercise of outstanding warrants (3)	2,422,231	\$ 0.20	\$ 484,446	\$ 59
Total Offering	2,422,231	\$ 0.20	\$ 484,446	\$ 59

Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “Securities Act”), the shares being registered (1) hereunder include such indeterminate number of shares of common stock as may become issuable as a result of stock splits, stock dividends or similar transactions.

Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the (2) Securities Act, based on the average of the high and low prices of the common stock of the registrant as reported on the Nasdaq Capital Market on December 21, 2018.

Consists of 25,000 shares of common stock issuable upon the exercise of outstanding warrants with an exercise (3) price of \$24.60 per share and 2,397,231 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of \$0.96 per share.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale of these securities is not permitted.

SUBJECT TO COMPLETION, DATED December 27, 2018

PROSPECTUS

2,422,231 SHARES OF COMMON STOCK

This prospectus relates to the resale from time to time of up to 2,422,231 shares of our common stock, par value \$0.001 per share, which are issuable upon the exercise of certain warrants held by the selling stockholders named in this prospectus. We are not selling any common stock under this prospectus and will not receive any proceeds from the sale of shares listed in this prospectus. We will, however, receive the net proceeds of any warrants exercised for cash in the future.

The selling stockholders may offer and sell the shares from time to time at varying prices and in a number of different ways as each selling stockholder may determine through public or private transactions or through other means described in the section entitled “Plan of Distribution” or a supplement to this prospectus. Each selling stockholder may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol “BPTH.” The last reported sale price of our common stock on the Nasdaq Capital Market on December 26, 2018 was \$0.158 per share.

Investing in our securities involves a high degree of risk. Before making an investment decision, you should review carefully and consider all of the information set forth in this prospectus and the documents incorporated by reference in this prospectus. See “Risk Factors” on page 9 of this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission (the “SEC”) nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2018.

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ABOUT THIS PROSPECTUS

This prospectus relates to the offering of up to 2,422,231 shares of our common stock issuable upon the exercise of outstanding warrants. Before buying any of the common stock that the selling stockholders are offering, we urge you to carefully read this prospectus, together with the information incorporated by reference as described under the headings “Where You Can Find More Information” and “Information Incorporated By Reference” in this prospectus. These documents contain important information that you should consider when making your investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representation. You should assume that the information in this prospectus is accurate only as of the dates on the front of this document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since those dates.

You should read this prospectus and the documents incorporated by reference in this prospectus when making your investment decision.

Unless the context requires otherwise, references in this prospectus 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.”

PROSPECTUS SUMMARY

This prospectus summary highlights selected information contained elsewhere in this prospectus or in documents incorporated by reference. This summary does not contain all of the information that you should consider before making an investment decision. You should carefully read the entire prospectus, including under the section titled “Risk Factors” and the documents incorporated by reference into this prospectus, before making an investment decision.

Our Company

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”) and in combination with decitabine.

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 2019.

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 by us 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 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 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 design and manufacture of RNAi nanoparticle drug products.

On April 3, 2018, we announced that interim data from Stage 1 of 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 to date in this study early anti-leukemic activity in nearly 50% of evaluable AML patients. Stage 1 of the open-label Phase 2 study evaluated 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 predetermined 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 from Stage 1 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, 47% showed some form of response, including stable disease and 24% having a complete response, to the combination treatment. The average age of patients in the study was 73.5 years old.

On August 27, 2018, we announced that the Company commenced Stage 2 of the efficacy portion of the Phase 2 clinical trial for AML. Based on the recommendations of the principal investigators of the study, we amended the protocol to change the dosing schedule in Stage 2 to that used in the Phase 1b study in relapsed and refractory AML patients as announced in April 2018. In the Phase 1b study, a greater amount of prexigebersen was administered prior to LDAC treatment starting at day 10 versus LDAC treatment starting on day four as was the case in Stage 1 of the Phase 2 study. In addition, the investigators endorsed the inclusion of a combination prexigebersen and decitabine cohort based on relatively new and positive data with this compound. Finally, the Company is in the process of adding three new sites in Europe to enhance patient enrollment. We currently plan to perform an interim analysis of each cohort once approximately 19 evaluable patients are reached in each cohort.

Recent Developments

At the 2018 Annual Meeting of Stockholders of the Company held on December 20, 2018, the Company’s stockholders approved an amendment to the Company’s Certificate of Incorporation (the “Certificate of Incorporation”) to effect a reverse stock split of the Company’s common stock, par value \$0.001 per share, at a ratio of up to 1-for 20, to be determined by the Company’s board of directors, subject to the authority of the board of directors to abandon such reverse stock split in its discretion. As of the date of this prospectus, the board of directors has not determined a reverse stock split ratio or whether to effect a reverse stock split. Although we expect that a reverse stock split would result in an increase in the market price of our common stock, it may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors detailed from time to time in the reports we file with the SEC.

As previously reported, on November 1, 2018, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market (“Nasdaq”) indicating that, based upon the closing bid price of the Company’s common stock for the last 30 consecutive business days, the Company did not meet the minimum bid price of \$1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Rule”). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an initial period of 180 calendar days, or until April 30, 2019, to regain compliance with the Minimum Bid Price Rule.

Corporate 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 Company, 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.

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 prospectus have been adjusted to give effect to the 1-for-10 reverse stock split.

Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357. Our Internet address is www.biopathholdings.com. None of the information on our website forms a part of, or incorporated by reference into, this prospectus.

Description of Prior Registered Offerings and Private Placements

The shares offered in this prospectus relate to the resale of an aggregate of 2,422,231 shares of our common stock underlying the Warrants (as defined below).

On July 5, 2016, we completed the closing of a registered direct offering (the “2016 Registered Direct Offering”) with certain institutional and accredited investors for the sale of an aggregate of 588,235 shares of our common stock and warrants to purchase up to 294,118 shares of our common stock for gross proceeds of approximately \$10.0 million. We also issued warrants to purchase up to 25,000 shares of our common stock, with an exercise price of \$24.60, exercisable from January 5, 2017 until January 5, 2022 (the “2016 Placement Agent Warrants”), to representatives of H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the 2016 Registered Direct Offering.

On September 25, 2018, we completed the closing of a registered direct offering (the “2018 Registered Direct Offering”) with certain institutional and accredited investors for the sale of an aggregate of 1,969,077 shares of our common stock and pre-funded warrants to purchase up to 292,461 shares of our common stock for gross proceeds of approximately \$1.5 million. In a concurrent private placement (the “2018 Private Placement”), we issued to the investors in the 2018 Registered Direct Offering warrants to purchase up to 2,261,538 shares of our common stock, with an exercise price of \$0.96, exercisable from March 25, 2019 until March 25, 2024 (the “Series A Warrants”). We also issued warrants to purchase up to 135,693 shares of common stock of our common stock, with an exercise price of \$0.96, exercisable from March 25, 2019 until September 20, 2023 (the “2018 Placement Agent Warrants” and together with the 2016 Placement Agent Warrants and the Series A Warrants, the “Warrants”), to representatives of H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the 2018 Registered Direct Offering and 2018 Private Placement.

THE OFFERING

Common Stock Offered by the Selling Stockholders Up to 2,422,231 shares of our common stock, par value \$0.001 per share, 25,000 of which are issuable at an exercise price of \$24.60 per share upon the exercise of the 2016 Placement Agent Warrants originally issued by us, and 2,397,231 of which are issuable at an exercise price of \$0.96 per share upon the exercise of the Series A Warrants and the 2018 Placement Agent Warrants originally issued by us, each as described above.

Use of Proceeds We are not selling any common stock under this prospectus and will not receive any proceeds from the sale of shares listed in this prospectus. We will, however, receive the net proceeds of any Warrants exercised for cash in the future. We currently expect to use such net proceeds, if any, for working capital and general corporate purposes.

Nasdaq Capital Market Symbol “BPTH”

Risk Factors An investment in our company involves a high degree of risk. Please refer to the sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements” and other information included or incorporated by reference in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

RISK FACTORS

An investment in our company involves a high degree of risk. Before you make a decision to invest in our securities, you should consider carefully the risks described in or incorporated by reference in this prospectus, including the risks and uncertainties discussed under the section titled “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K, and all other documents incorporated by reference into this prospectus, as updated by our subsequent filings under the Exchange Act of 1934, as amended (the “Exchange Act”).

Any of these risks could have a material adverse effect on our business, prospects, financial condition and results of operations. In any such case, the trading price of our securities could decline and you could lose all or part of your investment. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations. The risks described in or incorporated by reference in this prospectus also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See “Special Note Regarding Forward-Looking Statements.”

Risks Related to this Offering

Our common stock may be delisted from the Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

The listing standards of the Nasdaq Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of \$1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If we fail to comply with all listing standards applicable to issuers listed on the Nasdaq Capital Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from the Nasdaq Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

As previously reported, on November 1, 2018, we received a letter from Nasdaq indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of \$1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Minimum Bid Price

Rule. We have been provided an initial period of 180 calendar days, or until April 30, 2019, to regain compliance with the Minimum Bid Price Rule. The letter also indicated that if at any time before April 30, 2019 the closing bid price for our common stock is at least \$1.00 for a minimum of ten consecutive business days, Nasdaq will provide written notification to the Company that it complies with the Minimum Bid Price Rule. If we do not regain compliance with the Minimum Bid Price Rule by April 30, 2019, we may be eligible for a second compliance period of 180 calendar days, provided that we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and notify Nasdaq of our intention to cure the deficiency during such second compliance period, including by effecting a reverse stock split, if necessary. If we do not regain compliance with the Minimum Bid Price Rule by April 30, 2019 and are not eligible for a second compliance period at that time, Nasdaq will provide written notification to us that our common stock may be delisted. At that time, we may appeal Nasdaq's delisting determination to a Nasdaq hearings panel. If we timely appeal, our common stock would remain listed pending the panel's decision. There can be no assurance that, if we do appeal the delisting determination by Nasdaq to the panel, such appeal would be successful.

Special Note Regarding Forward-Looking Statements

This prospectus and the documents incorporated by reference into this prospectus contain “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 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 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 but not limited to risk factors contained in or incorporated by reference under the section titled “Item 1A. Risk Factors” to Part I of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2017 and other factors described elsewhere in this prospectus or in our current and future filings with 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. You should carefully read this prospectus, together with the information incorporated herein by reference as described under the section titled “Where You Can Find More Information,” completely and with the understanding that our actual future results may be materially different from what we expect. 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;

substantial doubt regarding our ability to continue as a going concern;

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;
- 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;
 - our need to raise additional capital;
 - the volatility of the trading price of our common stock;
 - our common stock being thinly traded;
- our ability to issue shares of common or preferred stock without approval from our stockholders;
 - our ability to pay cash dividends;

costs relating to public investigations, fines, enforcement actions and other sanctions by regulatory agencies if we do not comply with regulations applicable to public companies; and

- our ability to regain and maintain compliance with the listing standards of the Nasdaq Capital Market.

Any forward-looking statement made by us in this prospectus and the documents incorporated by reference into this prospectus 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.

Use of Proceeds

We are not selling any common stock under this prospectus and will not receive any proceeds from the sale of shares listed in this prospectus. We will, however, receive the net proceeds of any Warrants exercised for cash in the future. We currently expect to use such net proceeds, if any, for working capital and general corporate purposes. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares. We will not be paying any underwriting discounts or commissions in this offering.

SELLING STOCKHOLDERS

This prospectus covers an aggregate of up to 2,422,231 shares of our common stock that may be sold or otherwise disposed of by the selling stockholders. Such shares are issuable to the selling stockholders upon the exercise of the Warrants we issued to the selling stockholders in certain private placement transactions. See “Description of Prior Registered Offerings and Private Placements” above.

The following table sets forth certain information with respect to each selling stockholder, including (i) the shares of our common stock beneficially owned by the selling stockholder prior to this offering, (ii) the maximum number of shares being offered by the selling stockholder pursuant to this prospectus and (iii) the selling stockholder’s beneficial ownership after completion of this offering, assuming that all of the Warrants are exercised and all of the shares covered hereby (but none of the other shares, if any, held by the selling stockholders) are sold. The registration of the shares of common stock issuable to the selling stockholders upon the exercise of the Warrants does not necessarily mean that the selling stockholders will sell all or any of such shares.

The table is based on information supplied to us by the selling stockholders, with beneficial ownership and percentage ownership determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a selling stockholder and the percentage ownership of that selling stockholder, shares of common stock subject to warrants held by that selling stockholder that are exercisable as of December 21, 2018, or exercisable within 60 days after December 21, 2018, are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. The percentage of beneficial ownership after this offering is based on 13,309,833 shares outstanding on September 30, 2018.

The registration of these shares of common stock does not mean that the selling stockholders will sell or otherwise dispose of all or any of those securities. The selling stockholders may sell or otherwise dispose of all, a portion or none of such shares from time to time. We do not know the number of shares, if any, that will be offered for sale or other disposition by any of the selling stockholders under this prospectus. Furthermore, the selling stockholders may have sold, transferred or disposed of the shares of common stock covered hereby in transactions exempt from the registration requirements of the Securities Act since the date on which we filed this prospectus.

Under the terms of the Warrants, a selling stockholder may not exercise Warrants to the extent that such selling stockholder, together with its affiliates, would beneficially own, after such exercise, more than 4.99% of the shares of common stock then outstanding (subject to the right of the selling stockholder to increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%) and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered.

Substantially similar beneficial ownership limitations are found in other warrants to purchase common stock held by the selling stockholders. The number of shares in the second column below does not reflect these beneficial ownership limitations. The selling stockholders may sell all, a portion or none of their shares in this offering. See “Plan of Distribution” below.

To our knowledge and except as noted below, none of the selling stockholders has, or within the past three years has had, any position, office or other material relationship with us or any of our predecessors or affiliates.

Selling Stockholders	Number of Shares Beneficially Owned Prior to the Offering	Percent	Maximum Number Offered by Selling Stockholder (19)	Number of Shares Beneficially Owned After Completion of Offering (20)	Percent (20)
Bigger Capital Fund, LP (1) (2)	220,769	(9) 1.66 %	220,769	220,769	1.40 %
District 2 Capital Fund LP (1) (3)	310,000	(10) 2.33 %	310,000	310,000	1.97 %
Hudson Bay Master Fund Ltd. (1) (4)	414,531	(11) 3.06 %	192,308	414,531	2.60 %
Sabby Volatility Warrant Master Fund, Ltd. (1) (5)	278,841	(12) 2.05 %	1,538,461	278,841	1.74 %
Michael Vasinkevich (6)	0	(13) *	87,522	0	* %
Mark Viklund (6) (7)	625	(14) *	4,696	0	* %
Charles Worthman (6) (7)	250	(15) *	1,607	0	* %
Noam Rubinstein (6) (7)	3,125	(16) *	45,868	0	* %
James Cappuccio (7)	4,750	(17) *	4,750	0	* %
CVI Investments, Inc. (8)	16,250	(18) *	16,250	0	* %

*Less than 1%

(1) Series A Warrant holder.

Bigger Capital GP, LLC, the general partner of Bigger Capital Fund, LP, and Michael Bigger, the managing member of Bigger Capital GP, LLC, share voting and investment power over these securities. Each of Bigger Capital GP, LLC and Michael Bigger disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein.

District 2 GP LLC, the general partner of District 2 Capital LP, and Michael Bigger, the managing member of District 2 GP LLC, share voting and investment power over these securities. Each of District 2 GP LLC and Michael Bigger disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein.

Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities.

Sabby Management, LLC, the investment manager of Sabby Volatility Warrant Master Fund, Ltd., and Hal Mintz, manager of Sabby Management, LLC, share voting and investment power with respect to these securities. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein.

2018 Placement Agent Warrant holder. The 2018 Placement Agent Warrants were issued to the selling stockholder as a representative of H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the registered direct offering and concurrent private placement.

2016 Placement Agent Warrant holder. The 2016 Placement Agent Warrants were issued to the selling stockholder as a representative of H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the 2016 Registered Direct Offering.

(8)

Heights Capital Management, Inc., the authorized agent of CVI Investments, Inc., has voting and investment power over these securities. Martin Kobinger, in his capacity of as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI Investments, Inc. Mr. Kobinger disclaims beneficial ownership of these securities.

(9) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 220,769 shares of common stock. Excludes 220,769 shares of common stock underlying Series A Warrants, as the Series A Warrants do not become exercisable until March 25, 2019.

(10) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 310,000 shares of common stock. Excludes 310,000 shares of common stock underlying Series A Warrants, as the Series A Warrants do not become exercisable until March 25, 2019.

(11) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 192,308 shares of common stock and 222,223 shares of common stock underlying warrants with an exercise price of \$0.6108 per share. Excludes 192,308 shares of common stock underlying Series A Warrants, as the Series A Warrants do not become exercisable until March 25, 2019.

(12) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 106,618 shares of common stock underlying warrants with an exercise price of \$6.00 per share and 172,223 shares of common stock underlying warrants with an exercise price of \$0.6108 per share. Excludes 1,538,461 shares of common stock underlying Series A Warrants, as the Series A Warrants do not become exercisable until March 25, 2019.

(13) Based on information supplied to us by the selling stockholder as of December 4, 2018. Excludes 87,522 shares of common stock underlying 2018 Placement Agent Warrants, as the 2018 Placement Agent Warrants do not become exercisable until March 25, 2019.

(14) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 625 shares of common stock underlying 2016 Placement Agent Warrants. Excludes 4,071 shares of common stock underlying 2018 Placement Agent Warrants, as the 2018 Placement Agent Warrants do not become exercisable until March 25, 2019.

(15) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 250 shares of common stock underlying 2016 Placement Agent Warrants. Excludes 1,357 shares of common stock underlying 2018 Placement Agent Warrants, as the 2018 Placement Agent Warrants do not become exercisable until March 25, 2019.

(16) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 3,125 shares of common stock underlying 2016 Placement Agent Warrants. Excludes 42,743 shares of common stock underlying 2018 Placement Agent Warrants, as the 2018 Placement Agent Warrants do not become exercisable until March 25, 2019.

(17) Based on information supplied to us by the selling stockholder as of December 4, 2018. Includes 4,750 shares of common stock underlying 2016 Placement Agent Warrants.

(18) Based on information supplied to us by the selling stockholder as of December 12, 2018. Includes 16,250 shares of common stock underlying 2016 Placement Agent Warrants, which were transferred to the selling stockholder by H.C. Wainwright & Co., LLC and certain of its designees.

(19) Represents the maximum number of shares of common stock that may be offered by the selling stockholder based on the assumption that all of the outstanding Warrants held by the selling stockholder will be exercised for cash, irrespective of limitations on exercise.

(20) Represents the number of shares of common stock that will be beneficially owned by the selling stockholder after completion of this offering based on the assumptions that (i) all of the Warrants held by all selling stockholders will be exercised; (ii) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold and (iii) no other shares of common stock will be acquired or sold by the selling stockholders before completion of this offering. Applicable percentage ownership following the offering is based on 15,732,064 shares of common stock that would be outstanding assuming the exercise of all of the Warrants and all shares registered by this prospectus are sold in the offering.

Plan of Distribution

The selling stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus from time to time on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling the shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser in amounts to be negotiated.

In connection with a sale of the shares or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus, as supplemented or amended to reflect such transaction.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Because the selling stockholders may be deemed to be “underwriters” within the meaning of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act.

To our knowledge, there are currently no plans, arrangements or understandings between the selling stockholders and any underwriter, broker-dealer or agent regarding the sale of the shares covered by this prospectus by such selling stockholders. If any selling stockholder notifies us that a material arrangement has been entered into with an underwriter, broker-dealer or other agent for the sale of shares through a block trade, special offering or secondary distribution, we may be required to file a prospectus supplement pursuant to applicable SEC rules promulgated under the Securities Act.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from the sale of the shares by the selling stockholders. We will bear all costs, expenses and fees in connection with the registration of the shares.

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock is a summary. It is not complete and is subject to and qualified in its entirety by our certificate of incorporation and first amended and restated bylaws, each of which is incorporated by reference into this prospectus. See the sections titled “Where You Can Find More Information” and “Information Incorporated by Reference.” As of the date of this prospectus, our certificate of incorporation authorizes us to issue 200,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. As of September 30, 2018, there were 13,309,833 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

Holders of common stock are entitled to one vote for each share held in the election of directors and on all other matters submitted to a vote of stockholders. Cumulative voting of shares of common stock is prohibited. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election.

Subject to the prior rights of the holders of any outstanding preferred stock, holders of common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available therefor. Upon the liquidation, dissolution or winding up of our company, the holders of common stock are entitled to receive ratably the assets of our company remaining after payment of all liabilities and payment to holders of preferred stock if such preferred stock has an involuntary liquidation preference over the common stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable.

As of December 26, 2018, there were approximately 235 holders of record of our common stock.

Preferred Stock

The board of directors is authorized, without any further notice to or action of the stockholders, to issue 10,000,000 shares of preferred stock in one or more series and to determine the relative rights, preferences and privileges of the shares of any such series.

Limitation on Liability and Indemnification of Officers and Directors

Our certificate of incorporation and first amended and restated bylaws provide for indemnification of our officers and directors to the fullest extent permitted by Delaware law. Our certificate of incorporation and first amended and restated bylaws limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. We maintain directors and officers liability insurance.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Our Bylaws and Delaware Law

Some provisions of Delaware law and our certificate of incorporation and our first amended and restated bylaws contain provisions that could have the effect of delaying, deterring or preventing another party from acquiring or seeking to acquire control of us. These provisions are intended to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage anyone seeking to acquire control of us to negotiate first with our board of directors. However, these provisions may also delay, deter or prevent a change in control or other takeover of our company that our stockholders might consider to be in their best interests, including transactions that might result in a premium being paid over the market price of our common stock and also may limit the price that investors are willing to pay in the future for our common stock. These provisions may also have the effect of preventing changes in our management.

Our certificate of incorporation and first amended and restated bylaws include anti-takeover provisions that:

authorize our board of directors, without further action by the stockholders, to issue shares of preferred stock in one or more series, and with respect to each series, to fix the number of shares constituting that series and establish the rights and other terms of that series;

· establish advance notice procedures for stockholders to submit nominations of candidates for election to our board of directors and other proposals to be brought before a stockholders meeting;

· provide that our first amended and restated bylaws may be amended by our board of directors without stockholder approval;

· limit our stockholders' ability to call special meetings of stockholders;

· allow our directors to establish the size of the board of directors by action of the board, subject to a minimum of three members;

· provide that vacancies on our board of directors or newly created directorships resulting from an increase in the number of our directors may be filled only by a majority of directors then in office, even though less than a quorum; and

· do not give the holders of our common stock cumulative voting rights with respect to the election of directors.

Business Combinations

Section 203 of the Delaware General Corporation Law provides that we may not engage in certain "business combinations" with any "interested stockholder" for a three-year period following the time that the person became an interested stockholder, unless:

· prior to the time that person became an interested stockholder, our board of directors approved either the business combination or the transaction which resulted in the person becoming an interested stockholder;

· upon consummation of the transaction which resulted in the person becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding certain shares; or

· at or subsequent to the time the person became an interested stockholder, the business combination is approved by the board of directors and by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, consolidation, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an interested stockholder is a person who, together with that person's affiliates and associates, owns, or within the previous three years owned, 15% or more of our voting stock. However, in the case of our company, the sponsors and any of their respective permitted transferees receiving 15% or more of our voting stock, such stockholders will not be deemed to be interested stockholders regardless of the percentage of our voting stock owned by them. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us.

Reverse Stock Split

At the 2018 Annual Meeting of Stockholders of the Company held on December 20, 2018, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock, par value \$0.001 per share, at a ratio of up to 1-for 20, to be determined by the Company's board of directors, subject to the authority of the board of directors to abandon such reverse stock split in its discretion. As of the date of this prospectus, the board of directors has not determined a reverse stock split ratio or whether to effect a reverse stock split.

Listing

Our common stock is listed for trading on The Nasdaq Capital Market under the symbol “BPTH.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC, 6201 15th Avenue, Brooklyn, New York 11219. Its phone number is (800) 937-5449.

Legal Matters

The validity of the issuance of the securities offered hereby will be passed upon for us by Winstead PC, Houston, Texas.

Experts

The consolidated financial statements as of December 31, 2017 and 2016 and for the years then ended incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

Where You Can Find More Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the securities offered hereby, we refer you to the registration statement and the exhibits filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us. The SEC's Internet site can be found at <http://www.sec.gov>. In addition, we make available on or through our Internet site copies of these reports as soon as reasonably practicable after we electronically file or furnished them to the SEC. Our Internet site can be found at <http://www.biopathholdings.com>. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

INFORMATION INCORPORATED BY REFERENCE

We are incorporating by reference into this prospectus certain information that we file with the SEC, which means that we are disclosing important information to you by referring you to those documents. The information incorporated by reference is deemed to be part of this prospectus, except for information incorporated by reference that is superseded by information contained in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any statements in the prospectus or any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents set forth below that we have previously filed with the SEC:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017;

- our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30 and September 30, 2018;

- our Definitive Proxy Statement on Schedule 14A relating to our 2018 Annual Meeting of Stockholders, filed November 2, 2018;

- our Current Reports on Form 8-K filed with the SEC on February 5, 2018 (other than information furnished under Item 7.01 and exhibits related thereto), February 9, 2018 (other than information furnished under Item 7.01 and exhibits related thereto), February 26, 2018, September 21, 2018 (other than information furnished under Item 7.01 and exhibits related thereto); November 2, 2018 (other than information furnished under Item 7.01 and exhibits related thereto); and December 21, 2018; and

the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on March 5, 2014, as updated by our Current Report on Form 8-K filed with the SEC on January 6, 2015.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus or in a later filed document that is incorporated or deemed to be incorporated herein by reference modifies or replaces such information.

We also incorporate by reference all documents we file in the future pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the filing of the registration statement of which this prospectus is a part and prior to the effectiveness of such registration statement or (ii) after the date of this prospectus and until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K (except, in any such case, the portions furnished and not filed pursuant to Item 2.02, Item 7.01 or otherwise), as well as any proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. You may request a copy of these filings at no cost, by writing to or telephoning us at the following address:

Bio-Path Holdings, Inc.
Attention: Secretary
4710 Bellaire Boulevard, Suite 210
Bellaire, Texas 77401
(832) 742-1357

2,422,231 SHARES OF COMMON STOCK

, 2018

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PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth an estimate of the fees and expenses payable by the registrant in connection with the issuance and distribution of the securities being registered. All amounts are estimated except the SEC registration fee. All of the expenses below will be paid by us.

	AMOUNT
SEC registration fee	\$ 59
Printing and related expenses	\$ 2,500
Legal fees and expenses	\$ 20,000
Accounting fees and expenses	\$ 10,000
Miscellaneous expenses	\$ 1,000
Total	\$ 33,559

Item 14. Indemnification of Directors and Officers.

Section 102(b)(7) of the Delaware General Corporation Law (the "DGCL") permits a corporation to eliminate or limit the personal liability of its directors to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that to the fullest extent elimination or limitation of personal liability of directors is permitted by the DGCL, no director of the Company shall be liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director.

Section 145 of the DGCL permits a corporation to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is party or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not

opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our first amended and restated bylaws and our certificate of incorporation provide that each person (and the heirs, executors or administrators of such person) who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was a director or officer of the Company shall be indemnified and held harmless by the Company to the fullest extent permitted by applicable law. Our certificate of incorporation also states that we will pay or reimburse the reasonable expenses incurred in defending any such action, suit or proceeding in advance of its final disposition if we have received an undertaking by the person receiving such payment or reimbursement to repay all amounts advanced if it should be ultimately determined that he or she is not entitled to be indemnified.

We have entered into indemnification agreements with each of our directors. The contractual rights to indemnification provided by these indemnity agreements are subject to the limitations and conditions specified in such agreements.

The effect of the foregoing is to require us to indemnify our officers and directors for any claim arising against such persons in their official capacities if such person acted in good faith and in a manner that he or she reasonably believed to be in or not contrary to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors and officers, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

We have directors and officers insurance which includes insurance for claims against these persons brought under securities laws.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities issued by the Company since January 1, 2015 that were not registered under the Securities Act. Also included is the consideration received by the Company for such securities and information relating to the section of the Securities Act or rule of the SEC under which exemption from registration was claimed. 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. The following share and per share amounts, to the extent relating to periods prior to the 1-for-10 reverse stock split, have been adjusted to give effect to the 1-for-10 reverse stock split.

At the 2018 Annual Meeting of Stockholders of the Company held on December 20, 2018, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock, par value \$0.001 per share, at a ratio of up to 1-for 20, to be determined by our board of directors, subject to the authority of the board of directors to abandon such reverse stock split in its discretion. As of the date of this registration statement, the board of directors has not determined a reverse stock split ratio or whether to effect a reverse stock split. Accordingly, the following share and per share amounts have not been adjusted to reflect this proposed reverse stock split.

(1) On July 5, 2016, we completed the closing of the 2016 Registered Direct Offering with certain institutional and accredited investors for the sale of an aggregate of 588,235 shares of our common stock and warrants to purchase up to 294,118 shares of our common stock for gross proceeds of approximately \$10.0 million. We also issued 2016 Placement Agent Warrants to purchase up to 25,000 shares of our common stock, with an exercise price of \$24.60, exercisable from January 5, 2017 until January 5, 2022, to representatives of H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the 2016 Registered Direct Offering. The 2016 Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the

Securities Act and/or Regulation D promulgated thereunder. Each investor represented that it was an accredited investor, as defined in Rule 501 of Regulation D promulgated under the Securities Act. The shares offered in this prospectus include the resale of 25,000 shares of our common stock underlying the 2016 Placement Agent Warrants.

(2) On May 21, 2017, we entered into Warrant Exercise Agreements with certain holders of then-outstanding warrants (the "Original Warrants") exercisable for 441,176 shares of our common stock pursuant to which the holders agreed to exercise their Original Warrants at a negotiated exercise price equal to \$3.80 per share. In addition, we also issued to each exercising holder a new warrant ("New Warrants") to purchase shares of our common stock equal to the number of shares of common stock received by such holder upon exercise of its Original Warrants. The terms of the New Warrants were 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 Warrant Exercise Agreements and (ii) had an exercise price equal to \$6.00 per share. The New Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder. Each exercising holder represented that it was an accredited investor, as defined in Rule 501 of Regulation D promulgated under the Securities Act.

(3) On November 6, 2017, we completed the closing of a registered direct offering with several institutional and accredited investors for the sale of 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. We also issued warrants to purchase up to 16,000 shares of our common stock, with an exercise price of \$4.50, exercisable from May 6, 2018 until May 3, 2022 (the "2017 Placement Agent Warrants") Roth Capital Partners, LLC as part of its compensation as the placement agent for the registered direct offering. The 2017 Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder.

On September 25, 2018, we completed the closing of the 2018 Registered Direct Offering with certain institutional and accredited investors for the sale of an aggregate of 1,969,077 shares of our common stock and pre-funded warrants to purchase up to 292,461 shares of our common stock, with an exercise price of \$0.01, for gross proceeds of approximately \$1.5 million. In the concurrent 2018 Private Placement, we sold to each investor the Series A Warrants to purchase up to 2,261,538 shares of our common stock, with an exercise price of \$0.96, exercisable from March 25, 2019 until March 25, 2024. We also issued the 2018 Placement Agent Warrants to purchase up to 135,693 shares of our common stock, with an exercise price of \$0.96, exercisable from March 25, 2019 until (4) September 20, 2023, to representatives of H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the 2018 Registered Direct Offering and the concurrent 2018 Private Placement. The Series A Warrants and the 2018 Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder. Each investor represented that it was an accredited investor, as defined in Rule 501 of Regulation D promulgated under the Securities Act. The shares offered in this prospectus include the resale of the 2,397,231 shares of our common stock underlying the Series A Warrants and the 2018 Placement Agent Warrants.

Item 16. Exhibits.

(a) Exhibits

Exhibit Number	Exhibit
<u>2.1</u>	<u>Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company’s Current Report on Form 8-K filed on September 27, 2007).</u>
<u>3.1</u>	<u>Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company’s Current Report on Form 8-K filed on January 6, 2015).</u>
<u>3.2</u>	<u>Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed on February 9, 2018).</u>
<u>3.3</u>	<u>First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed on June 7, 2017).</u>
<u>4.1</u>	<u>Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company’s Annual Report on Form 10-K filed on March 16, 2015).</u>
<u>4.2</u>	<u>Warrant Agreement, dated April 25, 2008, by and between the Company and Randeep Suneja, M.D. (incorporated by reference to Exhibit 4.2 to the Company’s Annual Report on Form 10-K filed on March 31, 2014).</u>

4.3 Form of Warrant issued to Maxim Group LLC, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K on January 21, 2014).

4.4 Form of Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 29, 2016).

4.5 Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.5 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2016).

4.6 Form of New Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 22, 2017).

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- 4.7 Form of Warrant Amendment (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 19, 2017).
- 4.8 Form of Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 6, 2017).
- 4.9 Form of Warrant issued to Roth Capital Partners, LLC (incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 10-K filed on April 2, 2018).
- 4.10 Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 21, 2018).
- 4.11 Form of Series A Warrant issued to certain investors (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on September 21, 2018).
- 4.12 Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2018).
- 5.1* Opinion of Winstead PC.
- 10.1+ Employment Agreement – Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 19, 2008).
- 10.2+ Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed on December 10, 2008).
- 10.3+ First Amendment to First Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013).
- 10.4 Patent and Technology License Agreement, dated as of November 2, 2007, by and between the Company and the Board of Regents of The University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013).
- 10.5 Amendment No. 1 to the Patent and Technology Agreement, dated as of May 11, 2009, by and between the Company and the Board of Regents of the University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013).
- 10.6 Form of Securities Purchase Agreement by and between the Company, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 21, 2014).
- 10.7 Form of Waiver, Consent and Amendment to that certain Securities Purchase Agreement by and between Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K on January 21, 2014).
- 10.8+ First Amendment to Employment Agreement, dated March 26, 2014 – Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 26, 2014).

10.9 Lease Agreement dated April 16, 2014 by and between the Company and Pin Oak North Parcel TT, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2014).

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- 10.10 Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 16, 2015).
- 10.11 Controlled Equity OfferingSM Sales Agreement, dated June 24, 2015, by and between the Company and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on June 25, 2015).
- 10.12 Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 29, 2016).
- 10.13 Form of Warrant Exercise Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 22, 2017).
- 10.14 Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 6, 2017).
- 10.15 Form of Leak-Out Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 6, 2017).
- 10.16+ Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.17 Form of Incentive Stock Option Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.18 Form of Non-Qualified Stock Option Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.19 Form of Restricted Share Unit Award Agreement (Time-Vested) under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.20 Form of Restricted Share Unit Award Agreement (Performance-Based) under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.21 Form of Restricted Share Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.22 Form of Stock Appreciation Right Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on December 27, 2017).
- 10.23 Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2018).
- 21.1 Subsidiaries of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on April 2, 2018).

23.1* Consent of BDO USA, LLP, an independent registered public accounting firm.

23.2* Consent of Winstead PC (included in Exhibit 5.1).

24.1* Power of attorney (contained on the signature page).

* Filed herewith.

+ Management contract or compensatory plan.

(b) Financial statement schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of a prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the change in volume and price represents no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *Provided, however,* that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the undersigned registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 under the Securities Act;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement

relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bellaire, State of Texas, on December 27, 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 and Principal Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter H. Nielsen his or her true and lawful attorney-in-fact, with the power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including pre-effective amendments and post-effective amendments) to this registration statement, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

/s/ Peter H. Nielsen

Peter H. Nielsen

December 27,
2018

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President, Chief Executive Officer (Principal Executive Officer), Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) and Director

/s/ Heath W. Cleaver

Heath W. Cleaver

Director

December 27,
2018

/s/ Mark P. Colonnese

Mark P. Colonnese

Director

December 27,
2018

/s/ Paul D. Aubert

Paul D. Aubert

Director

December 27,
2018

/s/ Douglas P. Morris

Douglas P. Morris

Director and Secretary

December 27,
2018