

BIO-PATH HOLDINGS INC
Form S-1/A
March 19, 2019

As filed with the Securities and Exchange Commission on March 19, 2019

Registration No. 333-229049

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

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 | 2834 | 87-0652870 |
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (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: x

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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. "

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 (4) |
|---|-----------------------------|--|---|--------------------------------|
| Common Stock, par value \$0.001 per share, issuable upon exercise of outstanding warrants (3) | 552,684 | \$ 29.74 | \$ 16,436,822 | \$ 1,992 |
| Total Offering | 552,684 | \$ 29.74 | \$ 16,436,822 | \$ 1,992 |

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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 March 15, 2019.

(3) Consists of 552,684 shares of common stock issuable upon the exercise of outstanding warrants (including shares that may be issued to the holder in lieu of fractional shares).

(4) Of this amount, \$59 has already been paid.

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.

Explanatory Note

This Amendment No. 1 (this “Amendment”) to the Registration Statement on Form S-1 (333-229049) (the “Registration Statement”) is being filed to register additional shares of common stock issuable upon exercise of outstanding warrants that were issued in private placements by Bio-Path Holdings, Inc. (the “Company”) as described in the prospectus that forms a part of the Registration Statement. In addition, this Amendment is being filed to reflect the reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20 that we effected on January 17, 2019. All common stock share and per share amounts in the prospectus forming a part of the Registration Statement have been adjusted to give effect to the 1-for-20 reverse stock split, retrospectively.

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 March 19, 2019

PROSPECTUS

552,684 SHARES OF COMMON STOCK

This prospectus relates to the resale from time to time of up to 552,684 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 (including shares that may be issued to the holder in lieu of fractional shares). 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 March 15, 2019 was \$29.40 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 March , 2019.

TABLE OF CONTENTS

Prospectus

| | |
|--|-----------|
| <u>ABOUT THIS PROSPECTUS</u> | <u>5</u> |
| <u>PROSPECTUS SUMMARY</u> | <u>6</u> |
| <u>THE OFFERING</u> | <u>10</u> |
| <u>RISK FACTORS</u> | <u>11</u> |
| <u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u> | <u>12</u> |
| <u>USE OF PROCEEDS</u> | <u>14</u> |
| <u>SELLING STOCKHOLDERS</u> | <u>15</u> |
| <u>PLAN OF DISTRIBUTION</u> | <u>19</u> |
| <u>DESCRIPTION OF CAPITAL STOCK</u> | <u>21</u> |
| <u>LEGAL MATTERS</u> | <u>23</u> |
| <u>EXPERTS</u> | <u>23</u> |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u> | <u>23</u> |
| <u>INFORMATION INCORPORATED BY REFERENCE</u> | <u>23</u> |

ABOUT THIS PROSPECTUS

This prospectus relates to the offering of up to 552,684 shares of our common stock issuable upon the exercise of outstanding warrants (including shares that may be issued to the holder in lieu of fractional shares). 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 at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex’ i je ber’ sen), is in the efficacy portion of a Phase 2 clinical trial for acute myeloid leukemia (“AML”) in combination with low-dose cytarabine (“LDAC”) and in combination with decitabine. On March 6, 2019, we announced intended amendments to this Phase 2 clinical trial to, among other things, add prexigebersen in combination with decitabine for myelodysplastic syndrome (“MDS”) and close prexigebersen in combination with LDAC. In addition, preclinical efficacy studies are underway for triple combination prexigebersen, decitabine and Venclaxta in AML. Prexigebersen is also being studied in the safety portion of a Phase 2a clinical trial for chronic myeloid leukemia (“CML”) in combination with dasatinib. Prexigebersen was shown to enhance chemotherapy efficacy in preclinical solid tumor models, and we intend to file an Investigational New Drug (“IND”) application for prexigebersen in solid tumors in 2019.

Our second drug candidate, Liposomal Bcl-2 (“BP1002”), targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. We are currently preparing an 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/relapsed lymphoma and chronic lymphocytic leukemia (“CLL”) 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. 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-based products are available for out-licensing or partnering. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new nanoparticle antisense RNAi drug candidates. We have a new product identification template in place to define a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. As we expand, we will look at indications where a systemic delivery is needed and antisense RNAi nanoparticles can be used to slow, reverse or cure a disease, either alone or in combination with another drug. On 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, BP1002 and BP1003. We are developing RNAi antisense nanoparticle drug candidates based on our own patented technology to treat cancer and autoimmune disorders where targeting a single protein may be advantageous and result in reduced patient adverse effects as compared to small molecule inhibitors with off-target and non-specific effects. We have composition of matter and method of use intellectual property for the design and manufacture of antisense RNAi nanoparticle drug products.

On April 3, 2018, we released the interim data from Stage 1 of the Phase 2 clinical trial for AML in combination with LDAC. The prexigebersen and LDAC combination therapy was well-tolerated and showed early anti-leukemic activity in nearly 50% of evaluable AML patients, including four patients with complete remission (“CR”) and four with stable disease. On August 27, 2018, we announced that we commenced Stage 2 of the Phase 2 clinical trial for AML and added a cohort of patients to be treated with a combination of prexigebersen and decitabine, another AML frontline therapy. On March 6, 2019, we announced updates to the interim analysis from Stage 1 of the Phase 2 clinical trial. We announced that the efficacy profile improved to where 11 (65%) of the 17 evaluable patients had a response, including five (29%) who achieved CR, including one complete remission with incomplete hematologic recovery (“CRi”) and one morphologic leukemia free state, and six (35%) stable disease responses, including two patients who had greater than a 50% reduction in bone marrow blasts. The efficacy data from the 17 evaluable patients was very favorable compared to the reported CR, CRp (complete remission with incomplete platelet recovery) and CRi rates of 7-13% with LDAC treatment alone. Importantly, through investigation by the principal investigators, it was observed that 68% of patients were secondary AML patients, a difficult class to treat. On March 6, 2019, we also announced intended amendments to this Phase 2 clinical trial to, among other things, add prexigebersen in combination with decitabine for MDS and close prexigebersen in combination with LDAC.

Recent Developments

On January 14, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC relating to an underwritten public offering of 429,616 shares of our common stock for gross proceeds of approximately \$1.1 million under our shelf registration statement on Form S-3 (File No. 333-215205), which became effective on January 9, 2019 (the “2019 Underwritten Offering”). The offering price to the public in the 2019 Underwritten Offering was \$2.60 per share, and H.C. Wainwright & Co., LLC agreed to purchase the shares in the 2019 Underwritten Offering from the Company pursuant to the underwriting agreement at a price of \$2.418 per share. Additionally, we issued warrants to purchase up to 25,777 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as underwriter in connection with the 2019 Underwritten Offering. The 2019 Underwritten Offering closed on January 17, 2019. The net proceeds to us from the 2019 Underwritten Offering, after deducting the underwriting discounts and commissions and expenses and our estimated offering expenses, and excluding the proceeds, if any, from the exercise of the underwriter warrants, were approximately \$0.9 million.

On January 17, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on January 18, 2019.

On January 18, 2019, we entered into securities purchase agreements with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 648,233 shares of our common stock for gross proceeds of approximately \$1.7 million under our effective shelf registration statement on Form S-3 (File No. 333-215205), which became effective on January 9, 2019 (the “January 2019 Registered Direct Offering”). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants

to purchase up to 324,117 shares of our common stock (the “January 2019 Private Placement”). Additionally, we issued warrants to purchase up to 38,894 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the January 2019 Registered Direct Offering and the January 2019 Private Placement. The January 2019 Registered Direct Offering and the January 2019 Private Placement closed on January 23, 2019. The net proceeds to us from the offerings, after deducting the placement agent’s fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately \$1.5 million.

On March 12, 2019, we entered into securities purchase agreements with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 712,910 shares of our common stock for gross proceeds of approximately \$18.5 million under our effective shelf registration statement on Form S-3 (File No. 333-215205), which became effective on January 9, 2017 (the “March 2019 Registered Direct Offering”). Additionally, we issued warrants to purchase up to 42,775 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the March 2019 Registered Direct Offering. The March 2019 Registered Direct Offering closed on March 14, 2019. The net proceeds to us from the offerings, after deducting the placement agent’s fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately \$17.0 million.

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 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. In addition, as described above, on January 17, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on January 18, 2019. All common stock share and per share amounts in this prospectus have been adjusted to give effect to both the 1-for-10 reverse stock split and the 1-for-20 reverse stock split, retrospectively.

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 552,684 shares of our common stock issuable upon the exercise of the Warrants (as defined below) (including shares that may be issued to the holder in lieu of fractional shares).

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 29,412 shares of our common stock and warrants to purchase up to 14,706 shares of our common stock for gross proceeds of approximately \$10.0 million. We also issued warrants to purchase up to 1,250 shares of our common stock, with an exercise price of \$492.00 per share, 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. We are registering the resale of the shares issuable upon exercise of the 2016 Placement Agent Warrants.

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 98,454 shares of our common stock and pre-funded warrants to purchase up to 14,624 shares of our common stock for gross proceeds of approximately \$1.5 million. 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 113,077 shares of our common stock, with an exercise price of \$19.20 per share, exercisable from March 25, 2019 until March 25, 2024 (the “2018 Series A Warrants”). We also issued warrants to purchase up to 6,785 shares of our common stock, with an exercise price of \$19.20 per share, exercisable from March 25, 2019 until September 20, 2023 (the “2018 Placement Agent 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. We are registering the resale of the shares issuable upon exercise of the 2018 Series A Warrants and the 2018 Placement Agent Warrants.

On January 17, 2019, we completed the closing of the 2019 Underwritten Offering of 429,616 shares of our common stock for gross proceeds of approximately \$1.1 million. We also issued warrants to purchase up to 25,777 shares of our common stock, with an exercise price of \$3.25 per share, exercisable from January 17, 2019 until January 14, 2024 (the “2019 Underwriter Warrants”), to H.C. Wainwright & Co., LLC as part of its compensation as the underwriter for the 2019 Underwritten Offering. We are registering the resale of the shares issuable upon exercise of the 2019 Underwriter Warrants.

On January 23, 2019, we completed the closing of the January 2019 Registered Direct Offering with certain institutional and accredited investors for the sale of an aggregate of 648,233 shares of our common stock for gross proceeds of approximately \$1.7 million. In the concurrent January 2019 Private Placement, we issued to the investors in the 2019 Registered Direct Offering warrants to purchase up to 324,117 shares of our common stock, with an

exercise price of \$2.65 per share, exercisable from January 23, 2019 until July 24, 2024 (the “2019 Series A Warrants”). We also issued warrants to purchase up to 38,894 shares of our common stock, with an exercise price of \$3.3125 per share, exercisable from January 23, 2019 until January 18, 2024 (the “January 2019 Placement Agent Warrants”) to H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the January 2019 Registered Direct Offering and January 2019 Private Placement. We are registering the resale of the shares issuable upon exercise of the 2019 Series A Warrants and the January 2019 Placement Agent Warrants.

On March 14, 2019, we completed the closing of the March 2019 Registered Direct Offering with certain investors for the sale of an aggregate of 712,910 shares of our common stock for gross proceeds of approximately \$18.5 million. Additionally, we issued warrants to purchase up to 42,775 shares of our common stock, with an exercise price of \$32.4375 per share, exercisable from March 14, 2019 until March 12, 2024 (the “March 2019 Placement Agent Warrants”) to H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the March 2019 Registered Direct Offering. We are registering the resale of the shares issuable upon exercise of the March 2019 Placement Agent Warrants.

The 2016 Placement Agent Warrants, the 2018 Series A Warrants, the 2018 Placement Agent Warrants, the 2019 Underwriter Warrants, the 2019 Series A Warrants, the January 2019 Placement Agent Warrants and the March 2019 Placement Agent Warrants are collectively referred to herein as the “Warrants.”

THE OFFERING

| | |
|--|---|
| Common Stock Offered by the Selling Stockholders | Up to 552,684 shares of our common stock, par value \$0.001 per share, issuable upon exercise of the Warrants (including shares that may be issued to the holder in lieu of fractional shares). |
| 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.”

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, 2018 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;
- the highly-competitive nature of the pharmaceutical and biotechnology industry and our ability to compete effectively;
- the success of our plans to use collaboration arrangements to leverage our capabilities;
- our ability to retain and attract key personnel;
- the risk of misconduct of our employees, agents, consultants and commercial partners;
- disruptions to our operations due to expansions of our operations;
- the costs we would incur if we acquire or license technologies, resources or drug candidates;
- risks associated with product liability claims;
- our reliance on information technology systems and the liability or interruption associated with cyber-attacks or other breaches of our systems;
- our ability to use net operating loss carryforwards;
- provisions in our charter documents and state law that may prevent a change in control;
- work slowdown or stoppage at government agencies could negatively impact our business
- our need to complete extensive clinical trials and the risk that we may not be able to demonstrate the safety and efficacy of our drug candidates;
- risks that that our clinical trials may be delayed or terminated;
- our ability to obtain domestic and foreign regulatory approval for our drug candidates;

- changes in existing laws and regulations affecting the healthcare industry;
- our reliance on third parties to conduct clinical trials for our drug candidates;
- our ability to maintain orphan drug exclusivity for our drug candidates;
- our reliance on third parties for manufacturing our clinical drug supplies;
- risks associated with the manufacture of our drug candidates;
- our ability to establish sales and marketing capabilities relating to our drug candidates;
- market acceptance of our drug candidates;
- third-party payor reimbursement practices;
- our ability to adequately protect the intellectual property of our drug candidates;
- infringement on the intellectual property rights of third parties;
- costs and time relating to litigation regarding intellectual property rights;
- our ability to adequately prevent disclosure by our employees or others of trade secrets and other proprietary information;
- our need to raise additional capital;
- the volatility of the trading price of our common stock;

- our common stock being thinly traded;
- our ability to issue shares of common or preferred stock without approval from our stockholders;
- our ability to pay cash dividends;
- costs and expenses associated with being a public company;
- a material weakness identified in our internal controls over financial reporting; and
- our ability to maintain compliance with the listing standards of the Nasdaq Capital Market.

Any forward-looking statement made by us in this 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 552,684 shares of our common stock that may be sold or otherwise disposed of by the selling stockholders. Such shares (including shares that may be issued to the holder in lieu of fractional 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. When we refer to the “selling stockholders” in this prospectus, we mean the persons and entities listed in the table below, and their respective transferees, donees, pledgees, assignees and successors-in-interest who later come to hold any of the selling stockholders’ interests in shares of the common stock other than through a public sale.

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 March 15, 2019, or exercisable within 60 days after March 15, 2019, 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 2,507,239 shares outstanding on March 15, 2019.

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 Warrants or 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 (20) | Number of Shares Beneficially Owned After Completion of Offering (21) | Percent (21) |
|---|--|------|---------|---|---|---|-----------------|
| Bigger Capital Fund, LP | 11,039 | (1) | * | | 11,039 | 0 | * |
| District 2 Capital Fund LP | 15,500 | (2) | * | | 15,500 | 0 | * |
| Hudson Bay Master Fund Ltd | 44,983 | (3) | 1.76 | % | 44,983 | 0 | * |
| Sabby Volatility Warrant Master Fund, Ltd. | 82,255 | (4) | 3.18 | % | 76,924 | 5,331 | * |
| Michael Vasinkevich | 73,681 | (5) | 2.91 | % | 73,681 | 0 | * |
| Mark Viklund | 3,460 | (6) | * | | 3,460 | 0 | * |
| Charles Worthman | 1,155 | (7) | * | | 1,155 | 0 | * |
| Noam Rubinstein | 36,141 | (8) | 1.44 | % | 36,141 | 0 | * |
| James Capuccio | 238 | (9) | * | | 238 | 0 | * |
| CVI Investments, Inc. | 813 | (10) | * | | 813 | 0 | * |
| Armistice Capital Master Fund | 96,878 | (11) | 3.72 | % | 96,878 | 0 | * |
| Empery Asset Master, LTD | 28,028 | (12) | 1.11 | % | 28,028 | 0 | * |
| Empery Tax Efficient, LP | 11,511 | (13) | * | | 8,234 | 3,277 | * |
| Empery Tax Efficient II, LP | 47,109 | (14) | 1.84 | % | 45,238 | 1,871 | * |
| Gemini Asset Management, Inc. | 10,188 | (15) | * | | 10,188 | 0 | * |
| Intracoastal Capital, LLC | 24,450 | (16) | * | | 24,450 | 0 | * |
| Warberg WF VI LP | 5,094 | (17) | * | | 5,094 | 0 | * |
| Warberg WF VII LP | 17,300 | (18) | * | | 17,300 | 0 | * |
| Anson Investments Master Fund LP | 53,340 | (19) | 2.08 | % | 53,340 | 0 | * |

*Less than 1%

(1) Holds 2018 Series A Warrants. 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.

(2) Holds 2018 Series A Warrants. 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.

(3) Holds 2018 Series A Warrants and 2019 Series A Warrants. 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.

(4) Holds 2018 Series A Warrants. 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. Includes 5,331 shares of common stock issuable upon exercise of warrants with an exercise price of \$120.00 per share.

(5) Holds 2018 Placement Agent Warrants, 2019 Underwriter Warrants, January 2019 Placement Agent Warrants and March 2019 Placement Agent Warrants. These 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 or underwriter, as applicable, for the 2018 Registered Direct Offering, 2019 Underwritten Offering and 2019 Registered Direct Offering, respectively.

(6) Holds 2016 Placement Agent Warrants, 2018 Placement Agent Warrants, 2019 Underwriter Warrants, January 2019 Placement Agent Warrants and March 2019 Placement Agent Warrants. These 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 or underwriter, as applicable, for the 2016 Registered Direct Offering, 2018 Registered Direct Offering, 2019 Underwritten Offering and 2019 Registered Direct Offering, respectively.

(7) Holds 2016 Placement Agent Warrants, 2018 Placement Agent Warrants, 2019 Underwriter Warrants, January 2019 Placement Agent Warrants and March 2019 Placement Agent Warrants. These 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 or underwriter, as applicable, for the 2016 Registered Direct Offering, 2018 Registered Direct Offering, 2019 Underwritten Offering and 2019 Registered Direct Offering, respectively.

(8) Holds 2016 Placement Agent Warrants, 2018 Placement Agent Warrants, 2019 Underwriter Warrants, January 2019 Placement Agent Warrants and March 2019 Placement Agent Warrants. These 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 or underwriter, as applicable, for the 2016 Registered Direct Offering, 2018 Registered Direct Offering, 2019 Underwritten Offering and 2019 Registered Direct Offering, respectively.

(9) Holds 2016 Placement Agent Warrants. These 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.

(10) Holds 2016 Placement Agent Warrants. 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. These warrants were transferred to the selling stockholder by H.C. Wainwright & Co., LLC and certain of its designees.

(11) Holds 2019 Series A Warrants. The common shares held or to be acquired by Armistice Capital Master Fund, Ltd. may be deemed to be beneficially owned by (i) Armistice Capital, LLC, the Investment Manager of Armistice Capital Master Fund, Ltd. and (ii) Steven Boyd, the sole Managing Member of Armistice Capital, LLC and the Director of Armistice Capital Master Fund Ltd.

(12)

Holds 2019 Series A Warrants. Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd. (“EAM”), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. Empery Asset Management LP, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(13) Holds 2019 Series A Warrants. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP (“ETE”), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. Empery Asset Management LP, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(14) Holds 2019 Series A Warrants. Empery Asset Management LP, the authorized agent of Empery Tax Efficient II, LP (“ETE II”), has discretionary authority to vote and dispose of the shares held by ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE II. Empery Asset Management LP, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(15) Holds 2019 Series A Warrants. James Magro is the sole owner of Gemini Asset Management, Inc.

(16) Holds 2019 Series A Warrants. Mitchell P. Kopin (“Mr. Kopin”) and Daniel B. Asher (“Mr. Asher”), each of whom are managers of Intracoastal Capital LLC (“Intracoastal”), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities reported herein that are held by Intracoastal.

(17) Holds 2019 Series A Warrants. Daniel Warsh and Jonathan Blomberg are authorized representatives of Warberg WF VI LP and share voting and dispositive power over the securities held by such security holder.

(18) Holds 2019 Series A Warrants. Daniel Warsh and Jonathan Blomberg are authorized representatives of Warberg WF VII LP and share voting and dispositive power over the securities held by such security holder.

(19) Holds 2019 Series A Warrants. Anson Advisors Inc. and Anson Funds Management LP, the Co-Investment Advisers of Anson Investments Master Fund LP (“Anson”) hold voting and dispositive power over the Common Shares held by Anson. Bruce Winson is the managing member of Anson Management GP LLC, which is the general partner of Anson Funds Management LP. Moez Kassam and Amin Nathoo are directors of Anson Advisors Inc. Mr. Winson, Mr. Kassam and Mr. Nathoo each disclaim beneficial ownership of these Common Shares except to the extent of their pecuniary interest therein.

(20) 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.

(21) 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 3,059,923 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 March 15, 2019, there were 2,507,239 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 March 15, 2019, there were approximately 231 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.

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, 2018 and 2017 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, 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, 2018;
- our Current Reports on Form 8-K filed with the SEC on January 14, 2019; January 16, 2019; January 22, 2019 (other than information furnished under Item 7.01 and exhibits related thereto); February 5, 2019 and March 13, 2019 (other than information furnished under Item 7.01 and exhibits related thereto); 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 subsequently file in the future pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the effective date of the registration statement of which this prospectus forms a part prior to the termination of the offering. 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

552,684 SHARES OF COMMON STOCK

, 2019

25

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 | \$ 1,992 |
| Printing and related expenses | \$ 2,500 |
| Legal fees and expenses | \$ 20,000 |
| Accounting fees and expenses | \$ 10,000 |
| Miscellaneous expenses | \$ 1,000 |
| Total | \$ 35,492 |

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, 2016 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. In addition, as described above, on January 17, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on January 18, 2019. The following share and per share amounts, to the extent relating to periods prior to the reverse stock splits, have been adjusted to give effect to the reverse stock splits.

- 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 29,412 shares of our common stock and warrants to purchase up to 14,706 shares of our common stock for gross proceeds of approximately \$10.0 million. We also issued the 2016 Placement Agent Warrants to purchase up to 1,250 shares of our common stock, with an exercise price of \$492.00 per share, 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.
- (1) 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 the prospectus forming a part of this Registration Statement include the resale of 1,250 shares of our common stock issuable upon exercise of the 2016 Placement Agent Warrants (including shares that may be issued to the holder in lieu of fractional shares).

- On May 21, 2017, we entered into Warrant Exercise Agreements with certain holders of then-outstanding warrants (the "Original Warrants") exercisable for 22,059 shares of our common stock pursuant to which the holders agreed to exercise their Original Warrants at a negotiated exercise price equal to \$76.00 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 \$120.00 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.
- (2)

(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 66,667 shares of our common stock and warrants to purchase up to 33,334 shares of our common stock for gross proceeds of approximately \$4.0 million. We also issued common stock purchase warrants to purchase up to 800 shares of our common stock, with an exercise price of \$90.00 per share, exercisable from May 6, 2018 until May 3, 2022, to Roth Capital Partners, LLC as part of its compensation as the placement agent for the registered direct offering. The 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.

(4) 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 98,454 shares of our common stock and pre-funded warrants to purchase up to 14,624 shares of our common stock for gross proceeds of approximately \$1.5 million. In the concurrent 2018 Private Placement, we sold to each investor the 2018 Series A Warrants to purchase up to 113,077 shares of our common stock, with an exercise price of \$19.20 per share, exercisable from March 25, 2019 until March 25, 2024. We also issued the 2018 Placement Agent Warrants to purchase up to 6,785 shares of our common stock, with an exercise price of \$19.20 per share, exercisable from March 25, 2019 until 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 2018 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 the prospectus forming a part of this Registration Statement include the resale of 119,862 shares of our common stock issuable upon exercise of the 2018 Series A Warrants and the 2018 Placement Agent Warrants (including shares that may be issued to the holder in lieu of fractional shares).

On January 17, 2019, we completed the closing of the 2019 Underwritten Offering of 429,616 shares of our common stock for gross proceeds of approximately \$1.1 million. We also issued the 2019 Underwriter Warrants to purchase up to 25,777 shares of our common stock, with an exercise price of \$3.25 per share, exercisable from January 17, 2019 until January 14, 2024, to H.C. Wainwright & Co., LLC as part of its compensation as the (5) underwriter for the 2019 Underwritten Offering. The 2019 Underwriter 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. The shares offered in the prospectus forming a part of this Registration Statement include the resale of 25,777 shares of our common stock issuable upon exercise of the 2019 Underwriter Warrants (including shares that may be issued to the holder in lieu of fractional shares).

On January 23, 2019, we completed the closing of the 2019 Registered Direct Offering with certain institutional and accredited investors for the sale of an aggregate of 648,233 shares of our common stock for gross proceeds of approximately \$1.7 million. In the concurrent January 2019 Private Placement, we issued to the investors in the 2019 Registered Direct Offering the 2019 Series A Warrants to purchase up to 324,117 shares of our common stock, with an exercise price of \$2.65 per share, exercisable from January 23, 2019 until July 24, 2024. We also issued the January 2019 Placement Agent Warrants to purchase up to 38,894 shares of our common stock, with an exercise price of \$3.3125 per share, exercisable from January 23, 2019 until January 18, 2024, to (6) H.C. Wainwright & Co., LLC as part of its compensation as the placement agent for the January 2019 Registered Direct Offering and January 2019 Private Placement. The 2019 Series A Warrants and the January 2019 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 the prospectus forming a part of this Registration Statement include the resale of 363,011 shares of our common stock issuable upon exercise of the 2019 Series A Warrants and the January 2019 Placement Agent Warrants.

On March 12, 2019, we completed the closing of the March 2019 Registered Direct Offering with certain investors for the sale of an aggregate of 712,910 shares of our common stock for gross proceeds of approximately \$18.5 million. We also issued the March 2019 Placement Agent Warrants to purchase up to 42,775 shares of our common stock, with an exercise price of \$32.4375 per share, exercisable from March 14, 2019 until March 12, 2024, to H.C. Wainwright & Co., LLC as part of its compensation as the placement agent (7) for the March 2019 Registered Direct Offering. The March 2019 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. The shares offered in the prospectus forming a part of this Registration Statement include the resale of 42,775 shares of our common stock issuable upon exercise of the March 2019 Placement Agent Warrants.

Item 16. Exhibits.

(a) Exhibits

Exhibit

**Exhibit
Number**

2.1 Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).

3.1 Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).

3.2 Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2018).

28

- 3.3 First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 7, 2017).
- 3.4 Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
- 4.1 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).
- 4.2 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).
- 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).
- 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).
- 4.13 Form of Underwriter Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).

- 4.14 Form of Series A Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 22, 2019).
- 4.15 Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.15 to the Company's Annual Report on Form 10-K filed on March 19, 2019).
- 4.16 Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 13, 2019).
- 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).
- 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).
- 10.24 Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2019).
- 10.25 Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 13, 2019).
- 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)

* 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 Amendment No. 1 to registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bellaire, State of Texas, on March 19, 2019.

BIO-PATH HOLDINGS, INC.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 1 to 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 | March 19, 2019 |
| President, Chief Executive Officer (Principal Executive Officer), Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) and Director | |
| * | |
| Heath W. Cleaver | March 19, 2019 |
| Director | |
| * | |
| Mark P. Colonnese | March 19, 2019 |
| Director | |
| * | |
| Paul D. Aubert | March 19, 2019 |
| Director | |

*

Douglas P. Morris
Director and Secretary

March 19,
2019

* By: /s/ Peter H. Nielsen
Peter H. Nielsen, Attorney-In-Fact

34