

BIO-PATH HOLDINGS INC
Form 424B5
January 10, 2017

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-215205

PROSPECTUS

Up to \$25,000,000 of Common Stock

We have entered into a Controlled Equity OfferingSM sales agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”) relating to shares of common stock offered by this prospectus. In accordance with the terms of the Sales Agreement, we may offer and sell up to \$25,000,000 of our common stock from time to time through Cantor Fitzgerald, acting as sales agent. As of January 9, 2017, we had not issued nor sold any shares of our common stock pursuant to the Sales Agreement, our Registration Statement on Form S-3 (File No. 333-192102) and our related prospectus supplement dated June 24, 2016. Accordingly, we may offer and sell shares of our common stock having an aggregate offering price of up to \$25,000,000 pursuant to this prospectus.

Our common stock is traded on the NASDAQ Capital Market under the symbol “BPTH.” The last reported sale price of our common stock on the NASDAQ Capital Market on January 4, 2017 was \$1.27 per share.

Sales of our common stock, if any, under this prospectus may be made in sales deemed to be “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”). Subject to the terms of the Sales Agreement, Cantor Fitzgerald will act as sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between Cantor Fitzgerald and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor Fitzgerald will be entitled to compensation at a commission rate of 3.4% of the gross sales price per share sold. In connection with the sale of our common stock on our behalf, Cantor Fitzgerald will be deemed to be an “underwriter”

within the meaning of the Securities Act and the compensation of Cantor Fitzgerald will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Cantor Fitzgerald with respect to certain liabilities, including liabilities under the Securities Act or the Exchange Act of 1934, as amended (the "Exchange Act").

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 6 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 January 9, 2017.

TABLE OF CONTENTS

Prospectus

| | |
|--|----|
| <u>ABOUT THIS PROSPECTUS</u> | 2 |
| <u>PROSPECTUS SUMMARY</u> | 3 |
| <u>THE OFFERING</u> | 5 |
| <u>RISK FACTORS</u> | 6 |
| <u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u> | 7 |
| <u>USE OF PROCEEDS</u> | 8 |
| <u>DILUTION</u> | 9 |
| <u>PLAN OF DISTRIBUTION</u> | 10 |
| <u>DESCRIPTION OF CAPITAL STOCK</u> | 11 |
| <u>LEGAL MATTERS</u> | 13 |
| <u>EXPERTS</u> | 13 |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u> | 13 |
| <u>INFORMATION INCORPORATED BY REFERENCE</u> | 13 |

ABOUT THIS PROSPECTUS

This prospectus relates to the offering of our common stock. Before buying any of the common stock that we 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.

This prospectus describes the specific terms of the common stock we are offering and also adds to, and updates information contained in the documents incorporated by reference into this prospectus. To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference into this prospectus that was filed with the SEC before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. You should rely only on the information we have provided or incorporated by reference into this prospectus. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus—the statement in the document having the later date modifies or supersedes the earlier statement. We have not, and Cantor Fitzgerald has not, authorized anyone to provide you with different or additional information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in or incorporated by reference into this prospectus. You must not rely on any unauthorized information or representation.

We are offering to sell and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. 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. This prospectus does not constitute an offer, or a solicitation on our behalf or on behalf of the underwriters, to subscribe for and purchase any of the common stock and may not be used for or in connection with an offer or solicitation by anyone in any jurisdiction in which such an offer or solicitation is not authorized or to any person to whom it is unlawful to make such an offer or solicitation.

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 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 antisense 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 organs.

Using DNAbilize™ as a platform for drug development and manufacturing, we currently have two antisense drug candidates in development to treat a total of five different disease indications. Our lead drug candidate, Liposomal Grb2 (“BP1001”), targets the protein Grb2 and has entered the efficacy portion of a Phase II clinical trial for acute myeloid leukemia (AML) and is preparing to enter the safety segment of a Phase II clinical trial for blast phase and accelerated phase chronic myelogenous leukemia (CML). BP1001 is also in preclinical studies for solid tumors, including triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC).

Our second drug candidate, Liposomal Bcl2 (“BP1002”), targets the protein Bcl2, which is responsible for driving cell proliferation in up to 60% of all cancers. BP1002 is in preparation for an Investigational New Drug (IND) application.

We currently maintain an exclusive license agreement (the “License Agreement”) with The University of Texas, MD Anderson Cancer Center (“MD Anderson”), under which we license from MD Anderson the delivery technology platform and BP1001 and BP1002. We are developing antisense drug candidates to treat cancer and autoimmune

disorders where targeting a single protein may be advantageous and result in reduced adverse effects as compared to small molecule inhibitors with off-target and non-specific effects. We have composition of matter and method of use intellectual property for the manufacture of neutral charged DNA-liposome complexes.

BP1001

We have completed our Phase I clinical trials for BP1001 for indications for AML, CML, MDS and Acute Lymphoblastic Leukemia (ALL). On October 9, 2015, we announced the completion of Cohort 7, the first dosing cohort of the Phase Ib clinical trial, consisting of a 60 mg/m² dose of BP1001 in combination with LDAC. On March 3, 2016, we announced the completion of Cohort 8, the second dosing cohort of the Phase Ib clinical trial, consisting of a 90 mg/m² dose of BP1001 in combination with LDAC. On June 6, 2016, we announced data from the safety segment of the Phase II combination therapy of BP1001 and LDAC showed no dose limiting toxicities. Of the six evaluable patients, four patients completed more than two cycles of treatment, three patients achieved complete remission and two patients achieved partial remission. Pharmacokinetics of BP1001 demonstrated a half-life at 60 mg/m² of 30 hours, significantly better than the 90 mg/m² dose. The final analysis of these data, along with the demonstrated reductions in bone marrow blasts, suggested that 60 mg/m² was the appropriate dose for use in the Phase II trial. Administratively, this required us to reformat documents for the Phase II trial with the 60 mg/m² dose and resubmit for approvals with the FDA and site Institutional Review Boards, requiring additional time prior to starting the Phase II trial.

On November 2, 2016, we announced that the first patient in the efficacy portion of the Phase II trial was dosed. The full trial design includes approximately 54 evaluable patients with an interim analysis to be performed after 19 patients are treated with the combination. In the event the interim results exceed the primary endpoint in the number of patients that meet or exceed statistically determined thresholds, we may seek to convert the trial into a registration trial for accelerated approval. The multi-site trial will be conducted at leading cancer centers, among them are Weill Medical College of Cornell University, Baylor Scott & White Health, The University of Kansas and MD Anderson.

We have also initiated preclinical testing of BP1001 for the treatment of TNBC and IBC. Our plan is to develop BP1001 as a targeted therapy against TNBC and IBC. Our treatment goals are two-pronged: the first is to develop BP1001 as a tumor reduction agent in combination with other approved drugs in preoperative settings for TNBC and IBC patients, and the second is to develop BP1001 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients. Once the preclinical studies are completed, we believe that the observations that we learned from the original Phase I trial will help us increase the speed of progress for such Phase I trial in TNBC and IBC, as the toxicity profile of BP1001 is currently well-established.

BP1002

BP1002, also known by its scientific name as Liposomal Bcl2, is our second liposome delivered antisense drug candidate. BP1002 is intended to target the lymphoma and certain solid tumor markets. Clinical targets for BP1002 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. We believe that BP1002 has the potential to treat 40 to 60% of solid tumors.

DNAbilize™

DNAbilize™ technology is available for out-licensing. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. A significant amount of capital is expected to be allocated to in-license promising protein targets that can be developed as new liposomal antisense drug candidates. As we expand, we will look at indications where a systemic delivery is needed and antisense can be used to slow, reverse, or cure a disease, either alone or in combination with another drug.

We are interested in pursuing a wide-ranging, proactive licensing program to include co-development of specific liposomal antisense drug candidates, sub-licensing our delivery template for outside development of liposomal antisense drug candidates or out-licensing a partially-developed drug candidate for final development and marketing.

Corporate Information

We were originally incorporated in May 2000 as a Utah corporation under the name Ogden Golf Co. Corporation, but terminated our retail golf store operations in December 2006. In February 2008, we completed a reverse merger with Bio-Path Subsidiary. The name of Ogden Golf Co. Corporation was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol "BPTH." Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law.

Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357. 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.

THE OFFERING

| | |
|--|---|
| Common stock offered by us | Shares of our common stock having an aggregate offering price of up to \$25,000,000. |
| Common stock to be outstanding immediately after this offering (1) | Up to 115,330,263 shares (as more fully described in footnote (1) below), assuming sales of 19,685,039 shares of our common stock in this offering at an offering price of \$1.27 per share, which was the last reported sale price of our common stock on the NASDAQ Capital Market on January 4, 2017. The actual number of shares issued will vary depending on the sales price under this offering. |
| Manner of offering | “At-the-market” offering that may be made from time to time through our sales agent, Cantor Fitzgerald. See “Plan of Distribution” on page 10. |
| Use of proceeds | We currently expect to use the net proceeds from this offering, if any, for working capital and general corporate purposes. See “Use of Proceeds” on page 8. |
| 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,” “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. |

(1) The number of shares of common stock to be outstanding after this offering is based on 95,645,224 shares of common stock outstanding as of September 30, 2016, which excludes:

7,052,419 shares of common stock reserved for issuance upon the exercise of outstanding options granted under our First Amended 2007 Stock Incentive Plan, as amended (our “2007 Stock Incentive Plan”), with a weighted average exercise price of \$1.33 per share;

1,923,868 additional shares of common stock reserved for future issuance under our 2007 Stock Incentive Plan; and

5,951,176 shares of common stock that may be issued upon exercise of outstanding warrants with a weighted average exercise price of \$3.43 per share.

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 below, as well as 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.

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 discussed below 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.”

Resales of our common stock in the public market following the offering may cause its market price to fall.

We will issue common stock from time to time in connection with this offering. This issuance from time to time of these new shares of our common stock, or our ability to issue these shares of common stock in this offering, could result in resales of our common stock by our current stockholders concerned about the potential dilution of their holdings. If our stockholders sell substantial amounts of our common stock in the public market following this offering, the market price of our common stock could fall.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase. In addition, we may issue additional equity or convertible debt securities in the future, which may result in additional dilution to investors.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on an assumed offering price of \$1.27 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately \$0.99 per share in the net tangible book value of the common stock. See the section titled “Dilution” in this prospectus for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering. In addition, we have a significant number of stock options and warrants outstanding. To the extent that outstanding stock options or warrants

have been or may be exercised or other shares issued, you may experience further dilution.

Furthermore, to the extent we need to raise additional capital in the future and we issue additional shares of common stock or securities convertible or exchangeable for our common stock, our then-existing stockholders may experience dilution and the new securities may have rights senior to those of our common stock offered in this offering.

Our management has significant flexibility in using the net proceeds of this offering.

We intend generally to use the net proceeds from this offering, if any, for working capital and general corporate purposes. Our management will have significant flexibility in applying the net proceeds of this offering. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costly to raise funds in the future.

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, 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,” “strategy,” “future,” “likely,” “may,” “should,” “will” and variations of these words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties, and changes in circumstances, including but not limited to risk factors contained in or incorporated by reference under the section titled, “Risk Factors.” 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.

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

The amount of proceeds from this offering will depend upon the number of shares of our common stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the Sales Agreement with Cantor Fitzgerald as a source of financing.

We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. We currently intend to use the net proceeds from this offering, if any, for working capital and general corporate purposes. The amount and timing of these expenditures will depend on a number of factors, such as the timing, scope, progress and results of our research and development efforts, the timing and progress of any partnership efforts and the competitive environment for our product candidates.

Dilution

If you invest in our common stock, you will experience immediate and substantial dilution to the extent of the difference between the public offering price of our common stock and the adjusted net tangible book value per share of our common stock immediately after the offering.

Our net tangible book value per share is determined by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. The net tangible book value of our common stock as of September 30, 2016, was approximately \$8.4 million or \$0.09 per share, based on 95,645,224 shares of our common stock outstanding at September 30, 2016.

After giving effect to our sale in this offering of shares of our common stock in the aggregate amount of \$25,000,000 at an assumed public offering price of \$1.27 per share (the last reported sale price of our common stock on the NASDAQ Capital Market on January 4, 2017), and after deducting the placement agent fee and our estimated offering expenses payable by us, our net tangible book value as of September 30, 2016, would have been approximately \$32.6 million, or \$0.28 per share of common stock. This represents an immediate increase in net tangible book value of \$0.19 per share to existing stockholders and an immediate dilution of \$0.99 per share to new investors purchasing shares of common stock in this offering at the assumed public offering price. The following table illustrates this dilution on a per share basis:

| | |
|---|--------|
| Assumed public offering price per share | \$1.27 |
| Historical net tangible book value per share as of September 30, 2016 | \$0.09 |
| Increase in net tangible book value per share attributable to new investors | \$0.19 |
| As adjusted net tangible book value per share after this offering | \$0.28 |
| Dilution per share to new investors | \$0.99 |

The table above assumes for illustrative purposes that an aggregate of 19,685,039 shares of our common stock are sold at a price of \$1.27 per share, the last reported sale price of our common stock on the NASDAQ Capital Market on January 4, 2017, for aggregate gross proceeds of approximately \$25,000,000. The shares sold in this offering, if any, will be sold from time to time at various prices. An increase of \$0.50 per share in the price at which the shares are sold from the assumed public offering price of \$1.27 per share shown in the table above, assuming all of our common stock in the aggregate amount of approximately \$25,000,000 is sold at that price, would increase the dilution in net tangible book value per share to new investors in this offering to \$1.47 per share, after deducting commissions and estimated offering expenses payable by us. A decrease of \$0.50 per share in the price at which the shares are sold from the assumed public offering price of \$1.27 per share shown in the table above, assuming all of our common stock in the aggregate amount of approximately \$25,000,000 is sold at that price, would decrease the dilution in net tangible

book value per share to new investors in this offering to \$0.52 per share, after deducting commissions and estimated offering expenses payable by us. This information is supplied for illustrative purposes only.

The above discussion and table are based on 95,645,224 shares of our common stock outstanding as of September 30, 2016, which excludes:

7,052,419 shares of common stock reserved for issuance upon the exercise of outstanding options granted under our 2007 Stock Incentive Plan, with a weighted average exercise price of \$1.33 per share;

1,923,868 additional shares of common stock reserved for future issuance under our 2007 Stock Incentive Plan; and

5,951,176 shares of common stock that may be issued upon exercise of outstanding warrants with a weighted average exercise price of \$3.43 per share.

The above illustration of dilution per share to investors participating in this offering assumes no exercise of outstanding options to purchase our common stock or outstanding warrants to purchase shares of our common stock. To the extent that any of these outstanding warrants or options are exercised or we issue additional shares under our equity incentive plans, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

Plan of Distribution

We have entered into a Controlled Equity OfferingSM sales agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), under which we may issue and sell shares of our common stock having an aggregate gross sales price of up to \$25,000,000 from time to time through Cantor Fitzgerald acting as agent. As of January 9, 2017, we had not issued nor sold any shares of our common stock pursuant to the Sales Agreement, our Registration Statement on Form S-3 (File No. 333-192102) and our related prospectus supplement, dated June 24, 2016. Accordingly, we may offer and sell shares of our common stock having an aggregate offering price of up to \$25,000,000 pursuant to this prospectus. The Sales Agreement was filed as Exhibit 1.1 to our Current Report on Form 8-K filed with the SEC on June 25, 2014, and is incorporated by reference in this prospectus.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald may sell our common stock by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act. We may instruct Cantor Fitzgerald not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor Fitzgerald may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Cantor Fitzgerald commissions, in cash, for its services in acting as agent in the sale of our common stock. Cantor Fitzgerald will be entitled to compensation at a commission rate of 3.4% of the aggregate gross sales price per share sold. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse Cantor Fitzgerald for certain specified expenses, including the fees and disbursements of its legal counsel, in an amount not to exceed \$50,000. We estimate that the total expenses for the offering, excluding compensation and reimbursements payable to Cantor Fitzgerald under the terms of the Sales Agreement, will be approximately \$100,000.

Settlement for sales of common stock will occur on the third trading day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor Fitzgerald in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and Cantor Fitzgerald may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Cantor Fitzgerald will use its commercially reasonable efforts, consistent with its normal trading and sales practices, to solicit offers to purchase the common stock shares under the terms and subject to the conditions set forth in the Sales Agreement. In connection with the sale of the common stock on our behalf, Cantor Fitzgerald will be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of Cantor Fitzgerald will be deemed

to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor Fitzgerald against certain civil liabilities, including liabilities under the Securities Act.

Cantor Fitzgerald has entered into a fee sharing agreement with Maxim Group LLC (“Maxim”), pursuant to which Maxim will be entitled to receive compensation from Cantor Fitzgerald of approximately 1.0% of the gross sales price per share of our common stock sold under the Sales Agreement in consideration for Maxim’s services to us as a financial advisor under this offering. Other than serving as a financial advisor to us, Maxim will have no other obligations or responsibility in connection with the sale of common stock covered by this prospectus.

The offering of our common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, or (ii) termination of the Sales Agreement as permitted therein. We and Cantor Fitzgerald may each terminate the Sales Agreement at any time upon ten days’ prior notice.

Cantor Fitzgerald and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor Fitzgerald will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

This prospectus in electronic format may be made available on a website maintained by Cantor Fitzgerald and Cantor Fitzgerald may distribute this prospectus electronically.

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 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 January 4, 2017, there were 95,645,224 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.

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 bylaws provide for indemnification of our officers and directors to the fullest extent permitted by Delaware law. Our certificate of incorporation and 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 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 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 bylaws may be amended by our board of directors without stockholder approval;

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. Cantor Fitzgerald is being represented in connection with this offering by Latham & Watkins LLP, San Diego, California.

Experts

Our annual consolidated financial statements incorporated in this prospectus by reference to our Annual Report on Form 10-K for the year ended December 31, 2015, have been audited by Mantyla McReynolds, LLC, an independent registered public accounting firm, to the extent indicated in their report thereon. Such consolidated financial statements are incorporated by reference into this prospectus in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

Where You Can Find More Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any documents that we have filed with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the operation of the Public Reference Room. The SEC also 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>.

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, 2015;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30 and September 30, 2016;
- our Current Reports on Form 8-K filed with the SEC on June 30, August 1 and December 16, 2016; and

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

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

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

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

Bio-Path Holdings, Inc.

Attention: Secretary

4710 Bellaire Boulevard, Suite 210

Bellaire, Texas 77401

(832) 742-1357

Up to \$25,000,000

Common Stock

PROSPECTUS

January 9, 2017