

PROSPECTUS



3,500,000 SHARES OF COMMON STOCK
3,500,000 COMMON WARRANTS TO PURCHASE UP TO 3,500,000 SHARES OF COMMON STOCK
3,500,000 SHARES OF COMMON STOCK UNDERLYING THE COMMON WARRANTS

This is a best efforts public offering of 3,500,000 shares of our common stock, par value \$0.001 per share, together with warrants to purchase an aggregate of 3,500,000 shares of our common stock (the “Common Warrants”) at a combined public offering price of \$0.60 per share and one Common Warrant. Each share of our common stock is being sold together with a Common Warrant to purchase one share of our common stock. The exercise price of the Common Warrants will be \$0.60 per share, and the Common Warrants will be exercisable immediately upon issuance and will expire five years from the date of issuance. This offering also relates to the shares of common stock issuable upon exercise of any Common Warrants. The shares of common stock, and the accompanying Common Warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol “BPTH.” On August 2, 2023, the last reported sales price per share of our common stock on the Nasdaq Capital Market was \$0.7593. There is no established public trading market for the Common Warrants, and we do not expect a market to develop. In addition, we do not intend to list the Common Warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described in the section titled “Risk Factors” on page 6 of this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus.

	Per Share and Accompanying Common Warrant	Total
Offering price	\$0.600	\$2,100,000.00
Placement agent fees ⁽¹⁾	\$0.042	\$ 147,000.00
Proceeds, before expenses, to us ⁽²⁾	\$0.558	\$1,953,000.00

(1) Represents a cash fee equal to 7% of the aggregate purchase price paid by investors in this offering. In addition, we have agreed to reimburse the Placement Agent for certain expenses. See “Plan of Distribution” on page 16 of this prospectus for more information.

(2) The amount of the offering proceeds to us presented in this table does not give effect to the exercise, if any, of the Common Warrants.

We have engaged Roth Capital Partners, LLC as our exclusive placement agent (“Roth” or the “Placement Agent”) to use its reasonable best efforts to solicit offers to purchase our securities in this offering. The Placement Agent has no obligation to purchase any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. Because there is no minimum offering amount required as a condition to closing in this offering the actual public offering amount, Placement Agent’s fee, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above and throughout this prospectus. We have agreed to pay the Placement Agent the Placement Agent fees set forth in the table above. See “Plan of Distribution” in this prospectus for more information. There is no arrangement for funds to be received in escrow, trust or similar arrangement. Because there is no escrow account and no minimum number of securities or amount of proceeds, investors could be in a position where they have invested in us, but we have not raised sufficient proceeds in this offering to adequately fund the intended uses of the proceeds as described in this prospectus. We will bear all costs associated with the offering. This offering will end within three trading days from the date of this prospectus, but no later than August 14, 2023.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock and Common Warrants offered hereby is expected to take place on August 7, 2023, subject to satisfaction of certain conditions.

Roth Capital Partners

Prospectus dated August 3, 2023

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PROSPECTUS SUMMARY

This 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. This prospectus includes or incorporates by reference information about this offering, our business and our financial and operating data. You should carefully read the entire prospectus, including under the sections titled “Risk Factors” included herein, and the documents incorporated by reference into this prospectus, before making an 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.”

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 lipid bilayer having neutral charge. We believe this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. *In vivo*, the DNAbilize[®] delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of target proteins in blood diseases and solid tumors. Through testing in numerous animal studies and treatment in over 140 patients, our DNAbilize[®] drug candidates have demonstrated an excellent safety profile. DNAbilize[®] is a registered trademark of the Company.

Using DNAbilize[®] as a platform for drug development and manufacturing, we currently have four drug candidates in development to treat at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex’ i je ber’ sen), which targets growth factor receptor-bound protein 2 (Grb2), initially started the efficacy portion of a Phase 2 clinical trial for untreated acute myeloid leukemia (“AML”) patients in combination with low-dose cytarabine (“LDAC”). The interim data released on March 6, 2019 showed that 11 (65%) of the 17 evaluable patients had a response, including five (29%) who achieved complete remission (“CR”), inclusive of one CR 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. However, DNA hypomethylating agents are now the most frequently used agents in the treatment of elderly AML patients in the U.S. and Europe. As a result, Stage 2 of the Phase 2 trial in AML was amended to remove the combination treatment of prexigebersen and LDAC and replace it with the combination treatment of prexigebersen and decitabine, a DNA hypomethylating agent, for treatment of a second cohort of untreated AML patients. Since decitabine is also used as a treatment for relapsed/refractory AML patients, a cohort of relapsed/refractory AML patients was also added to the study.

The U.S. Food and Drug Administration (“FDA”) granted approval of venetoclax in combination with LDAC, decitabine or azacytidine (the latter two drugs are DNA hypomethylating agents) as frontline therapy for newly diagnosed AML in adults who are 75 years or older, or who have comorbidities precluding intensive induction chemotherapy. We believe this approval of the frontline venetoclax and decitabine combination therapy provides an opportunity for combining prexigebersen with the combination therapy for the treatment of *de novo* AML patients. Preclinical efficacy studies for the triple combination treatment of prexigebersen, decitabine and venetoclax in AML have been successfully completed. In the preclinical efficacy studies, four AML cancer cell lines were treated with three different combinations of decitabine, venetoclax and prexigebersen. Decrease in AML cell viability was the primary measure of efficacy. The triple combination of decitabine, venetoclax and prexigebersen showed significant improvement in efficacy in three of the four AML cell lines. Based on these results, we believe that adding prexigebersen to the treatment combination of decitabine and venetoclax could lead to improved efficacy in AML patients. Accordingly, we further amended Stage 2 of this Phase 2 clinical trial to add the triple combination treatment comprised of prexigebersen, decitabine and venetoclax.

Our approved amended Stage 2 for this Phase 2 clinical trial currently has three cohorts of patients. The first two cohorts will treat patients with the triple combination of prexigebersen, decitabine and venetoclax. The first cohort will include untreated AML patients, and the second cohort will include relapsed/refractory AML patients. Finally, the third cohort will treat relapsed/refractory AML patients, who are venetoclax-resistant or -intolerant, with the two-drug combination of prexigebersen and decitabine. The full trial design plans have approximately 98 evaluable patients for the first cohort having untreated AML patients with a planned preliminary interim review performed after 19 evaluable patients and a formal interim analysis after 38 evaluable patients. The full trial design plans have approximately 54 evaluable patients for each of the second cohort, having relapsed/refractory AML patients, and the third cohort, having AML patients who are venetoclax-resistant or -intolerant, in each case with a planned interim review performed after 19 evaluable patients. The study is anticipated to be conducted at up to ten clinical sites in the U.S., and Gail J. Roboz, MD, is the national coordinating Principal Investigator for the Phase 2 trial. Dr. Roboz is a professor of medicine and director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University (the “Weill Medical College”) and the New York-Presbyterian Hospital in New York City. On August 13, 2020, we announced the enrollment and dosing of the first patient in this approved amended Stage 2 of the Phase 2 clinical trial.

On April 5, 2021, we announced the successful completion of the safety run-in of Stage 2 of the Phase 2 clinical study. In the safety run-in of the triple combination, six evaluable patients were treated with the combination of prexigebersen, decitabine and venetoclax. These patients included four relapsed/refractory AML patients, and two newly diagnosed AML patients. In the preliminary safety data review, five of the patients (83%) responded to treatment, including four (67%) achieving CR and one (17%) achieving CRi. Recent publications provide that response (CR + CRi) rates to combination treatment with decitabine and venetoclax (but without prexigebersen) are 42 to 52% for relapsed/refractory AML patients and 0 to 39% for relapsed/refractory secondary AML patients. Response rates to frontline treatment with decitabine and venetoclax (but without prexigebersen) are 62 to 71% for newly diagnosed AML patients. These preliminary data, presented at the 2021 American Society of Hematology Annual Meeting, showed the treatment was well-tolerated and there were no dose limiting toxicities attributed to prexigebersen. Three patients remained on treatment for more than one cycle.

On August 1, 2023, we announced interim data for the first two cohorts of the amended Stage 2 of the Phase 2 clinical trial. Fourteen newly diagnosed patients were evaluable in the first cohort and treated with at least one cycle of the prexigebersen, decitabine and venetoclax combination therapy. All patients in the first cohort (median age 75) were adverse risk by 2017 European LeukemiaNet (“ELN”) guidelines (n=10) or secondary AML (n=4). Prexigebersen was well-tolerated, and adverse events (“AEs”) were generally consistent with decitabine and venetoclax treatment and/or for AML. Twelve of the 14 evaluable patients (86%) achieved CR/CRi and two (14%) achieved partial remission (“PR”). In total, 100% of the evaluable patients had a response to treatment. The complete remission rate (CR/CRi) of 86% for the evaluable patients in the first cohort is significantly higher than complete remission (CR/CRi) rates of 62% for newly diagnosed patients treated with the frontline combination treatment of decitabine and venetoclax. Fourteen refractory/relapsed evaluable AML patients in the second cohort were treated with at least one cycle of the prexigebersen, decitabine and venetoclax combination therapy. All patients in the second cohort (median age 56.5) were adverse risk by 2017 ELN guidelines (n=11) or secondary AML (n=2). Prexigebersen was well-tolerated, and AEs were generally consistent with decitabine and venetoclax treatment and/or for AML. Eight of the 14 evaluable patients (57%) achieved CR/CRi, two (14%) achieved PR and three (22%) achieved stable disease. In total, 93% of the evaluable patients in the second cohort had a response to treatment. The complete remission rate (CR/CRi) of (57%) for the evaluable refractory and relapsed patients in the second cohort is significantly higher than complete remission (CR/CRi) rates (21%) for refractory/relapsed patients treated with the combination treatment of decitabine and venetoclax. Based on this preliminary data, we currently plan to pursue FDA expedited programs for Fast Track and Breakthrough Therapy designations, and we are evaluating whether to seek to expand Stage 2 of the Phase 2 clinical trial in Europe.

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. On November 21, 2019, we announced that the FDA cleared an Investigational New Drug (“IND”) application for BP1002 for an initial Phase 1 clinical trial to evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia

patients. The Phase 1 clinical trial is being conducted at the Georgia Cancer Center while two additional clinical trial sites are currently being processed for inclusion in the study, The University of Texas Southwestern and New York Medical College.

Additionally, preclinical studies suggest that the combination of BP1002 with decitabine is efficacious in venetoclax-resistant leukemia and lymphoma cells. An abstract of the preclinical study was presented at the 2021 American Association for Cancer Research (“AACR”) Annual Meeting. On August 24, 2021, we announced that the FDA cleared an IND application for BP1002 for an initial Phase 1/1b clinical trial to evaluate the ability of BP1002 to treat refractory/relapsed AML patients, including venetoclax-resistant patients. The Phase 1/1b clinical trial is being conducted at several leading cancer centers in the United States, including the Weill Medical College, The University of Texas MD Anderson Cancer Center (“MD Anderson”), Scripps Health and The University of California at Los Angeles Cancer Center. Gail J. Roboz, M.D., will serve as the national coordinating Principal Investigator for the Phase 1/1b trial. On October 24, 2022, we announced the enrollment and dosing of the first patient in the Phase 1/1b clinical trial.

Our third drug candidate, Liposomal STAT3 (“BP1003”), targets the STAT3 protein and is currently in IND enabling studies as a potential treatment of pancreatic cancer, non-small cell lung cancer (“NSCLC”) and AML. Preclinical models have shown BP1003 to inhibit cell viability and STAT3 protein expression in NSCLC and AML cell lines. Further, BP1003 successfully penetrated pancreatic tumors *ex vivo* and significantly enhanced the efficacy of gemcitabine, a treatment for patients with advanced pancreatic cancer, in a pancreatic cancer patient derived tumor model. An abstract of the preclinical study was presented at the 2019 AACR Annual Meeting. Our lead indication for BP1003 is pancreatic cancer due to the severity of this disease and the lack of effective, life-extending treatments. For example, pancreatic adenocarcinoma is projected to be the second most lethal cancer behind lung cancer by 2030. Typical survival for a metastatic pancreatic cancer patient is about three to six months from diagnosis. Additionally, an abstract of the preclinical study demonstrating that BP1003 enhanced the sensitivity of breast and ovarian cancer cells to chemotherapy was presented at the 2022 AACR Annual Meeting. We have successfully completed several IND enabling studies of BP1003 and have one additional IND enabling study to complete. Once the additional study is successfully completed, our goal is to file an IND and initiate the first-in-humans Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors, including pancreatic cancer and NSCLC.

In addition, a modified product named BP1001-A, our fourth drug candidate, has shown to enhance chemotherapy efficacy in preclinical solid tumor models. Results of the preclinical study were published in the scientific journal *Oncotarget* in July 2020. BP1001-A incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties. On October 27, 2021, we announced that the FDA cleared an IND application for BP1001-A for an initial Phase 1/1b clinical trial in patients with advanced or recurrent solid tumors, and on December 7, 2022, we announced the enrollment and dosing of the first patient in the Phase 1/1b clinical trial. On July 17, 2023, we announced completion of the first cohort of the dose escalation portion of the Phase 1/1b clinical trial. The Phase 1/1b clinical trial is being conducted at several leading cancer centers in the United States, including MD Anderson, Karmanos Cancer Institute, Mary Crowley Cancer Research and Holy Cross Hospital, Maryland.

Our DNAbilize[®] technology-based products are available for out-licensing or partnering. We intend to apply our drug technology template to new disease-causing protein targets to develop new liposomal antisense drug candidates for inclusion in our pipeline that meet scientific, preclinical and commercial criteria and file new patents on these targets. We expect that these efforts will include collaboration with key scientific opinion leaders in the field of study and include developing drug candidates for diseases other than cancer. As we expand our drug development programs, 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.

We have certain intellectual property as the basis for our current drug products in clinical development, prexigebersen, BP1002, BP1003 and BP1001-A. 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.

Recent Developments

In connection with this offering, the Company also entered into warrant amendment agreements (the “Warrant Amendment Agreements”) with certain institutional accredited investors in this offering. Under the Warrant Amendment Agreements, the Company agreed to amend certain existing warrants to purchase up to an aggregate of 800,000 shares of the Company’s common stock that were previously issued on November 9, 2022 at an exercise price of \$2.85 per share, such that effective upon the closing of this offering, the amended warrants will have a reduced exercise price equal to \$0.7593 per share.

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 the Company was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the Nasdaq Capital Market under the ticker symbol “BPTH.” Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law. Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357. 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	3,500,000 shares on a “best efforts” basis.
Common Warrants offered by us	Common Warrants to purchase an aggregate of 3,500,000 shares of common stock. Each share of our common stock is being sold together with a Common Warrant to purchase one share of our common stock. The exercise price of the Common Warrants will be \$0.60 per share, and the Common Warrants will be exercisable immediately upon issuance and will expire five years from the date of issuance. This offering also relates to the shares of common stock issuable upon exercise of Common Warrants. There is no established public trading market for the Common Warrants and we do not expect a market to develop. In addition, we do not intend to list the Common Warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.
Common stock to be outstanding immediately after this offering ⁽¹⁾	11,460,164 shares, assuming exercise of any Common Warrants issued in this offering.
Offering Price	\$0.60 per share and accompanying Common Warrant.
Use of proceeds	We currently expect to use the net proceeds from this offering for working capital and general corporate purposes. See “Use of Proceeds.”
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 our securities.
Nasdaq Capital Market Symbol	“BPTH”
<hr/> <p>(1) The number of shares of common stock to be outstanding after this offering is based on 7,960,164 shares of our common stock outstanding as of March 31, 2023, which excludes, as of such date:</p> <ul style="list-style-type: none"> • 657,408 shares of common stock reserved for issuance upon the exercise of outstanding options granted under our equity incentive plans with a weighted average exercise price of \$11.67 per share; • 1,300,000 additional shares of common stock reserved for future issuance under our 2022 Stock Incentive Plan (our “2022 Stock Incentive Plan”); • 1,200,531 shares of common stock that may be issued upon exercise of outstanding warrants with a weighted average exercise price of \$7.03 per share; and • 3,500,000 shares of common stock issuable upon exercise of the Common Warrants to be issued to the investors in this offering with an exercise price of \$0.60 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 Securities 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.

Risks Related to this Offering

There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

With limited exceptions, we are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

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

We currently intend to use the net proceeds from this offering 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.

Warrants are speculative in nature, and holders of the warrants offered and sold in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock.

There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants offered and sold in this offering. Consequently, there can be no assurance whether it will ever be profitable for holders to exercise their warrants. In addition, until holders of the warrants offered and sold in this offering acquire shares of our common stock upon exercise of their warrants, holders will have no rights with respect to the shares of our common stock issuable upon exercise of their warrants. Upon exercise of their warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

There is no public market for the Common Warrants being offered in this offering.

There is no established public trading market for the Common Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Common Warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the Common Warrants will be limited.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, if at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our drug development efforts or other operations.

As of March 31, 2023, we had an accumulated deficit of \$96.8 million. To date, we have not generated any revenue from the sale of our drug candidates and we do not expect to generate any revenue from sales of our drug candidates for the foreseeable future. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. As of March 31, 2023, we had a cash balance of \$6.7 million. We do not believe

that our available cash at March 31, 2023 will be sufficient to meet obligations and fund our liquidity and capital expenditure requirements for the next 12 months from March 31, 2023. The Company's ability to continue as a going concern is dependent upon obtaining funding through one or more sources as described above within the next 12 months to meet its planned obligations and pay its liabilities. Even if this offering is successful, we must raise additional funds in order to continue operating our business.

We may finance our foreseeable cash requirements through cash on hand, debt financings and public or private equity offerings. Additionally, we may seek collaborations and license arrangements for our drug candidates. We may seek to access the public or private equity markets whenever conditions are favorable. We currently have no lines of credit or other arranged access to debt financing. If we are unable to obtain funding due to unfavorable terms or market conditions, management has determined that it can reduce spending on its day-to-day operations, sell laboratory assets and temporarily delay planned activities if needed. However, our ability to continue as a going concern is dependent upon obtaining funding through one or more sources described above within the next 12 months to meet our planned obligations and pay our liabilities. We estimate that we will receive net proceeds of approximately \$1.7 million from the sale of the securities offered by us in this offering and after deducting the estimated Placement Agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Common Warrants issued pursuant to this offering. In addition, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

Our ongoing future capital requirements will depend on numerous factors, including:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the rate of progress, results and costs of completion of ongoing preclinical testing of our drug candidates;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical tests of our drug candidates that we may initiate;
- the costs to obtain adequate supply of the compounds necessary for our drug candidates;
- the costs of obtaining regulatory approval of our drug candidates;
- the scope, prioritization and number of drug development programs we pursue;
- the costs for preparing, filing, prosecuting, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies and the costs to develop those products and technologies;
- the costs of future commercializing activities, including product sales, marketing, manufacturing and distribution, of any of our drug candidates or other products for which marketing approval has been obtained;
- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us; and
- competing technological and market developments.

Any additional fundraising efforts may divert our management from their day to day activities, which may adversely affect our ability to develop and commercialize our drug candidates. Our ability to raise additional funds will depend, in part, on the success of our product development activities and other factors related to financial, economic and market conditions, many of which are beyond our control. There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. If adequate funds are not available on a timely basis, we may be forced to:

- delay, reduce the scope of or eliminate one or more of our drug development programs;
- relinquish, license or otherwise dispose of rights to technologies, drug candidates or products that we would otherwise seek to develop or commercialize ourselves at an earlier stage or on terms that are less favorable than might otherwise be available; or
- liquidate and dissolve the Company.

If our operating plans change, we may require additional capital sooner than planned. Such additional financing may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan.

This is a best efforts offering, no minimum amount of securities is required to be sold.

The Placement Agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities being offered in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities or amount of proceeds that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to fund for our operations, as described under the heading “*Use of Proceeds*” on page 11 of this prospectus.

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 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 incorporated by reference under “Item 1A. Risk Factors” to Part I of our [Annual Report on Form 10-K for the fiscal year ended December 31, 2022](#) and other factors described elsewhere in this prospectus or in our current and future filings with the Securities and Exchange Commission (the “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 by reference in this prospectus as described under the sections 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;
- the impact, risks and uncertainties related to global pandemics, including the COVID-19 pandemic, and actions taken by governmental authorities or others in connection therewith;
- 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/or 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;
- our ability to maintain effective 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 expect to receive net proceeds from this offering of approximately \$1.7 million, after deducting the estimated Placement Agent fee and the estimated offering expenses payable by us, excluding the proceeds we may receive from the exercise of the Common Warrants issued in this offering. We cannot predict when or if the Common Warrants will be exercised. It is possible that the Common Warrants may expire and may never be exercised. Because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus.

We currently intend to use the net proceeds from this offering for working capital and general corporate purposes. As of the date of this prospectus, we cannot specify with certainty all of the particular uses of the proceeds from this offering. Accordingly, we will retain broad discretion over the use of such proceeds.

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 31, 2023, there were 7,960,164 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 June 21, 2023, there were approximately 191 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 $\frac{2}{3}$ % 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. 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.

Transfer Agent and Registrar

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

Listing

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

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 3,500,000 shares of our common stock and Common Warrants to purchase up to 3,500,000 shares of our common stock. We are also offering the shares of common stock issuable from time to time upon exercise of the Common Warrants offered hereby.

Common Stock

The material terms and provisions of our common stock are described under the heading “Description of Capital Stock” in this prospectus.

Common Warrants

The following summary of certain terms and provisions of Common Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Common Warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Common Warrants for a complete description of the terms and conditions of the Common Warrants.

Duration and Exercise Price. Each Common Warrant offered hereby will have an initial exercise price per share equal to \$0.60. The Common Warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Common Warrants will be issued separately from the common stock and will be held separately immediately thereafter. A Common Warrant to purchase one share of our common stock will be issued for every share of common stock purchased in this offering.

Exercisability. The Common Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Common Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder’s Common Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Common Warrants. No fractional shares of common stock will be issued in connection with the exercise of a Common Warrant. In lieu of fractional shares, we will round down to the next whole share.

Cashless Exercise. If, at the time a holder exercises its Common Warrants, a registration statement registering the issuance of the shares of common stock underlying the Common Warrants under the Securities Act is not then effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Common Warrants.

Transferability. Subject to applicable laws, a Common Warrant in book entry form may be transferred at the option of the holder through the facilities of the Depository Trust Company and common warrants in physical form may be transferred upon surrender of the Common Warrant to the warrant agent together with the appropriate instruments of transfer. Pursuant to a warrant agency agreement between us and Equiniti Trust Company, LLC, as warrant agent, the Common Warrants initially will be issued in book-entry form and will be represented by one or more global certificates deposited with The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Exchange Listing. There is no established public trading market for the Common Warrants, and we do not expect a market to develop. In addition, we do not intend to list the Common Warrants on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the Common Warrants will be limited.

Right as a Stockholder. Except as otherwise provided in the Common Warrants or by virtue of such holder’s ownership of shares of our common stock, the holders of the Common Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Common Warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the form of Common Warrant, and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Common Warrants will be entitled to receive upon exercise of the Common Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Common Warrants immediately prior to such fundamental transaction.

PLAN OF DISTRIBUTION

We have entered into a placement agency agreement dated August 3, 2023 with Roth Capital Partners, LLC, as exclusive placement agent, with respect to the securities being offered hereby. Under the terms of the placement agency agreement, Roth is not purchasing the securities offered by us in this offering, and is not required to sell any specific number or dollar amount of securities, but will assist us in this offering on a reasonable best efforts basis. The terms of this offering were subject to market conditions and negotiations between us, Roth and prospective investors. Roth will have no authority to bind us by virtue of the placement agency agreement. We may not sell the entire amount of securities offered pursuant to this prospectus supplement.

We will enter into a securities purchase agreement directly with the institutional investors, at the investor's option, who purchase our securities in this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

The placement agency agreement provides that the Placement Agent's obligations are subject to the conditions contained in the placement agency agreement.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about August 7, 2023. There is no minimum number of securities or amount of proceeds that is a condition to closing of this offering.

Placement Agent Fees and Expenses

Upon the closing of this offering, we will pay the Placement Agent a cash transaction fee equal to 7.0% of the aggregate gross proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the Placement Agent for its out-of-pocket expenses incurred in connection with this offering, including the fees and expenses of the counsel for the Placement Agent, up to \$100,000.

The following table shows the public offering price, Placement Agent fees and proceeds, before expenses, to us, assuming the purchase of all the securities we are offering.

	Per Share and Accompanying Common Warrant
Public offering price	\$ 0.600
Placement Agent fees	\$ 0.042
Proceeds, before expenses, to us	\$ 0.558

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding Placement Agent fees, will be approximately \$211,000, all of which are payable by us. This figure includes the Placement Agent's accountable expenses, including, but not limited to, legal fees for Placement Agent's legal counsel, that we have agreed to pay at the closing of the offering up to an aggregate expense reimbursement of \$100,000.

Indemnification

We have agreed to indemnify the Placement Agent against liabilities relating to this offering arising under the Securities Act and the Exchange Act, liabilities arising from breaches of some or all of the representations and warranties contained in the placement agency agreement, and to contribute to payments that the Placement Agent may be required to make for these liabilities.

Lock-Up Agreements

We and our executive officers, directors and certain holders of 5% or more of the outstanding shares of common stock expect to enter into lock up agreements with us prior to the commencement of this offering

pursuant to which each of these persons or entities, for a period of ninety (90) days from the effective date of the registration statement of which this prospectus forms a part, without our prior consent, agree not to offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise), directly or indirectly, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act, any shares of our common stock or securities convertible, or exercisable into, shares of our common stock.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the Placement Agent. In connection with the offering, the Placement Agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on the Placement Agent's website and any information contained in any other website maintained by the Placement Agent is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the Placement Agent in its capacity as placement agent and should not be relied upon by investors.

Regulation M

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent. Under these rules and regulations, the Placement Agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Determination of Offering Price and Warrant Exercise Price

The actual public offering price of the securities we are offering, and the exercise price of the Common Warrants that we are offering, were negotiated between us, the placement agent and the investors in the offering based on the trading price of our common stock prior to the offering, among other things. Other factors that were considered in determining the public offering price of the securities we are offering, as well as the exercise price of the Common Warrants included our history and prospects, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Other Compensation

If this offering is not consummated prior to August 9, 2023, then if within six (6) months following the termination or expiration of our engagement with the Placement Agent, we complete any sale of equity or equity-linked securities for which the Placement Agent is not acting as underwriter or placement agent to any of the investors that the Placement Agent introduced to us or with which the Placement Agent conducted discussions on our behalf, subject to specified exceptions, then we are required to pay to the Placement Agent a commission equal to 3.5% of the proceeds from such offering.

Other Relationships

From time to time, the Placement Agent and its affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of

business, for which they have received and may continue to receive customary fees and commissions. The Placement Agent served as our exclusive placement agent in connection with our registered public offering we consummated in November 2022, for which it received compensation.

The Nasdaq Capital Market Listing

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

Transfer Agent and Registrar

The transfer agent for our common stock to be issued in this offering is Equiniti Trust Company, LLC.

Offer Restrictions Outside the United States

European Economic Area

In relation to each member state of the European Economic Area, no offer of securities which are the subject of the offering has been, or will be made to the public in that Member State, other than under the following exemptions under the Prospectus Directive:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the Representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities referred to in (a) to (c) above shall result in a requirement for the Company or the placement agent to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of securities is made or who receives any communication in respect of an offer of securities, or who initially acquires any shares of our securities will be deemed to have represented, warranted, acknowledged and agreed to and with the placement agent and the Company that (1) it is a “qualified investor” within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any shares of our securities acquired by it as a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, the securities acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the placement agent has been given to the offer or resale; or where our securities have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those securities to it is not treated under the Prospectus Directive as having been made to such persons.

The Company, the placement agent and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

This prospectus has been prepared on the basis that any offer of our securities in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly, any person making or intending to make an offer in that Member State of our securities which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or the placement agent to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the placement agent have authorized, nor do they authorize, the making of any offer of securities in circumstances in which an obligation arises for the Company or the placement agent to publish a prospectus for such an offer.

For the purposes of this provision, the expression an “offer of our securities to the public” in relation to any of our securities in any Member State means the communication in any form and by any means of

sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State. The above selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to our securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company or our securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of our securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of our securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of our securities.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (“DFSA”). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (“ASIC”), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the “Corporations Act”) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of our securities may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring our securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law;
- (d) as specified in Section 276(7) of the SFA; or
- (e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the placement agent is not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Winstead PC, Houston, Texas. Pryor Cashman LLP, New York, New York is acting as counsel for the Placement Agent in connection with certain legal matters related to this offering.

EXPERTS

The consolidated financial statements of Bio-Path Holdings, Inc. appearing in Bio-Path Holdings, Inc.'s [Annual Report \(Form 10-K\) for the year ended December 31, 2022](#) have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 2 to the consolidated financial statements), included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference 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 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, 2022](#);
- [our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023](#);
- [our Definitive Proxy Statement on Schedule 14A relating to our 2022 Annual Meeting of Stockholders, filed October 28, 2022](#); and
- [the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on March 5, 2014, including all amendments and reports filed for purposes of updating such description](#).

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, 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



3,500,000 SHARES OF COMMON STOCK
3,500,000 COMMON WARRANTS TO PURCHASE UP TO 3,500,000 SHARES OF COMMON STOCK
3,500,000 SHARES OF COMMON STOCK UNDERLYING THE COMMON WARRANTS

PROSPECTUS

Roth Capital Partners

August 3, 2023
