

PROSPECTUS SUPPLEMENT
(To Prospectus dated June 14, 2022)



800,000 SHARES OF COMMON STOCK

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering to certain institutional accredited investors 800,000 shares of our common stock, par value \$0.001 per share.

In a concurrent private placement, we are also selling to such investors warrants to purchase up to 800,000 shares of our common stock (the "Common Warrants"), which represent 100% of the number of shares of our common stock being purchased in this offering. Each Common Warrant will be exercisable for one share of our common stock at an exercise price of \$2.85 per share, will be exercisable beginning six months after the date of issuance and will have a term of five and one-half years from the date of issuance. The Common Warrants and the shares of our common stock issuable upon the exercise of the Common Warrants (the "Common Warrant Shares") are being offered pursuant to the exemptions provided in Section 4(a)(2) under the Securities Act of 1933, as amended, and Rule 506(b) promulgated thereunder, and they are not being offered pursuant to this prospectus supplement and the accompanying prospectus.

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.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "BPTH." On November 4, 2022, the last reported sales price per share of our common stock on the Nasdaq Capital Market was \$2.85. As of November 6, 2022, the aggregate market value of our outstanding common stock held by non-affiliates was \$27,079,446, based on 7,160,164 shares of outstanding common stock, of which 7,126,170 shares are held by non-affiliates, and the last reported sale price of our common stock of \$3.80 per share on September 14, 2022. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75,000,000. We have also registered the offer and sale of up to \$3,000,000 million worth of our common stock pursuant to the terms of an "at-the-market" offering program and a prospectus dated June 14, 2022, as supplemented and amended by a prospectus supplemented dated July 29, 2022, but have not sold any shares of common stock pursuant to such prospectus and prospectus supplement as of the date hereof. We have not sold any securities pursuant to General Instruction 1.B.6 of Form S-3 during the 12 calendar month period that ends on and includes the date hereof.

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 S-7 of this prospectus supplement and under similar headings in the other documents that are incorporated by reference into this prospectus supplement.

	Per Share		Total	
Offering price	\$	2.50	\$	2,000,000
Placement agent fees (1)	\$	0.175	\$	140,000.00
Proceeds, before expenses, to us (2)	\$	2.325	\$	1,860,000.00

- (1) In addition, we have agreed to reimburse the placement agent for certain offering-related expenses as described under the "Plan of Distribution" on page S-11 of this prospectus supplement.
- (2) The amount of the offering proceeds to us presented in this table does not give effect to the sale or exercise, if any, of the Common Warrants being issued in the concurrent private placement.

We have retained Roth Capital Partners, LLC to act as our exclusive placement agent in connection with this offering. The placement agent 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. We have agreed to pay the placement agent a cash fee equal to 7% of the gross proceeds received by the Company in the offering. In addition, we have agreed to reimburse the placement agent for certain offering-related expenses as described under the "Plan of Distribution" on page S-11 of this prospectus supplement.

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 supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Delivery of the securities offered hereby is expected to take place on or about November 9, 2022, subject to satisfaction of certain conditions.

Roth Capital Partners

Prospectus supplement dated November 6, 2022

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Prospectus

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the U.S. Securities and Exchange Commission utilizing a “shelf” registration process. This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus as well as the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, gives more general information about securities we may offer from time to time, some of which does not apply to this offering. This prospectus supplement and the accompanying prospectus incorporate by reference important business and financial information about us that is not included in or delivered with this prospectus supplement and the accompanying prospectus.

You should rely only on the information we have provided or incorporated by reference in this prospectus supplement or in the accompanying prospectus. If information in this prospectus supplement is inconsistent with the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on this prospectus supplement; provided that 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 in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or the applicable prospectus supplement. You must not rely on any unauthorized information or representation. You should assume that the information in this prospectus supplement and accompanying prospectus is accurate only as of the dates on the front of the respective document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus when making your investment decision.

Unless the context requires otherwise, references in this prospectus supplement or the accompanying prospectus to “we,” “our,” “us,” “the Company” and “Bio-Path” refer to Bio-Path Holdings, Inc. and its wholly-owned subsidiary. Bio-Path Holdings, Inc.’s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as “Bio-Path Subsidiary.”

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere in this prospectus supplement, in the accompanying 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 supplement and the accompanying prospectus include or incorporate by reference information about this offering, our business and our financial and operating data. You should carefully read the entire prospectus supplement, the accompanying prospectus, including under the sections titled "Risk Factors" included therein, and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, before making an investment decision.

Our Company

We are a clinical and preclinical stage oncology-focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target-specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNAbilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating *in vivo*, incorporated inside of a 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 125 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 preliminary 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 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 CR 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.

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 that will evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients. The Phase 1 clinical trial is being conducted at several leading cancer centers, including The University of Texas MD Anderson Cancer Center (“MD Anderson Cancer Center”) and the Georgia Cancer Center. On November 19, 2020, we announced the enrollment and dosing of the first patient in the Phase 1 clinical trial.

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 that will evaluate the ability of BP1002 to treat refractory/relapsed AML patients. The Phase 1/1b clinical trial is anticipated to be conducted at several leading cancer centers in the United States, including the Weill Medical College, MD Anderson Cancer Center, 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 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 successfully completed several IND enabling studies of BP1003 in 2021 and have one additional IND enabling study to complete. Once the additional study is successfully completed, our goal is to file an IND as soon as the first half of 2023. Based on the filing of the IND, we expect to 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. In late 2019, we filed an IND application to initiate a Phase 1/1b clinical trial of BP1001-A in patients with solid tumors, including ovarian, endometrial, pancreatic and breast cancer. Ovarian cancer is one of the most common types of gynecologic malignancies, with approximately 50% of all cases occurring in women older than 63 years. On October 27, 2021, we announced that the FDA cleared the IND application for BP1001-A for the initial Phase 1/1b clinical trial, which allows us to proceed with next steps to open the clinical trial.

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 nanoparticle antisense RNAi drug candidates. We have a new product identification template in place to define a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. As we expand 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.

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.

The Offering

Common stock offered by us	800,00 shares of our common stock, par value \$0.001 per share.
Common stock to be outstanding immediately after this offering (1)	7,960,164 shares (assuming that we sell the maximum number of shares of common stock offered in this offering and excluding shares issuable upon the exercise of the Common Warrants to be issued in the concurrent private placement).
Offering price per share	\$2.50 per share.
Concurrent private placement of Common Warrants	In a concurrent private placement, we are selling to the institutional investors warrants to purchase up to 800,000 shares of our common stock (the “Common Warrants”), which represent 100% of the number of shares of our common stock being purchased in this offering. Each Common Warrant will be exercisable for one share of our common stock at an exercise price of \$2.85 per share, will be exercisable beginning six months after the date of issuance and will have a term of five and one-half years from the date of issuance. The Common Warrants and the shares of our common stock issuable upon the exercise of the Common Warrants (the “Common Warrant Shares”) are being offered pursuant to the exemptions provided in Section 4(a)(2) under the Securities Act of 1933, as amended (the “Securities Act”), and Rule 506(b) promulgated thereunder, and they are not being offered pursuant to this prospectus supplement and the accompanying prospectus.
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 supplement and the accompanying prospectus for a discussion of factors you should carefully consider before investing our securities.
Nasdaq Capital Market Symbol	“BPTH” 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.

(1) The number of shares of common stock to be outstanding after this offering is based on 7,160,164 shares of our common stock outstanding as of June 30, 2022, which excludes as of such date:

- 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;
- 18,724 additional shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan;
- 400,531 shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of \$15.39 per share; and
- 800,000 shares of common stock issuable upon exercise of the Common Warrants to be issued in the concurrent private placement with an exercise price of \$2.85 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 supplement and the accompanying 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 supplement and accompanying 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.

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 generally 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying 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,” “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, 2021](#) and other factors described elsewhere in this prospectus supplement, the accompanying prospectus or in our current and future filings with 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 supplement and the accompanying prospectus, together with the information incorporated by reference herein and therein 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. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith;
- our lack of significant revenue to date, our history of recurring operating losses and our expectation of future operating losses;
- our need for substantial additional capital and our need to delay, reduce or eliminate our drug development and commercialization efforts if we are unable to raise additional capital;
- the highly-competitive nature of the pharmaceutical and biotechnology industry and our ability to compete effectively;
- the success of our plans to use collaboration arrangements to leverage our capabilities;
- our ability to retain and attract key personnel;
- the risk of misconduct of our employees, agents, consultants and commercial partners;
- disruptions to our operations due to expansions of our operations;
- the costs we would incur if we acquire or license technologies, resources or drug candidates;
- risks associated with product liability claims;
- our reliance on information technology systems and the liability or interruption associated with cyber-attacks or other breaches of our systems;
- our ability to use net operating loss carryforwards;
- provisions in our charter documents and state law that may prevent a change in control;
- work slowdown or stoppage at government agencies could negatively impact our business;
- our need to complete extensive clinical trials and the risk that we may not be able to demonstrate the safety and efficacy of our drug candidates;
- risks that 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 supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying 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 placement agent fees and estimated offering expenses payable by us, excluding the proceeds we may receive from the exercise of the Common Warrants issued in the concurrent private placement.

We currently intend to use the net proceeds from this offering for working capital and general corporate purposes.

However, the amount and timing of what we actually spend for these purposes may vary and will depend on a number of factors, including our future revenue and cash generated by operations, if any, and the other factors described in “Risk Factors.” Accordingly, our management will have discretion and flexibility in applying the net proceeds of this offering.

PLAN OF DISTRIBUTION

Pursuant to an engagement letter dated as of November 6, 2022, we have retained Roth Capital Partners, LLC (“Roth”) to act as our exclusive placement agent in connection with this offering. Under the terms of the engagement letter, 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 engagement letter. We may not sell the entire amount of securities offered pursuant to this prospectus supplement.

Roth proposes to arrange for the sale of the securities we are offering pursuant to this prospectus supplement and accompanying prospectus to one or more investors through securities purchase agreements directly between the purchasers and us. We will only sell to investors who have entered into securities purchase agreements.

Delivery of the securities offered hereby is expected to take place on or about November 9, 2022, subject to satisfaction of certain conditions.

We have agreed to pay Roth a cash fee equal to 7% of the gross proceeds received from investors who purchase securities in the offering. In addition, subject to FINRA Rule 5110(f)(2)(d)(i), we have also agreed to reimburse the placement agent at closing up to a maximum aggregate amount of \$50,000 for expenses in connection with this offering.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the shares sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares by the placement agent acting as principal. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not 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 it has completed its participation in the distribution.

Indemnification

We have agreed to indemnify the placement agent and certain other persons against certain liabilities under the Securities Act relating to or arising out of the placement agent’s activities under the placement agency agreement. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

Electronic Distribution

This prospectus supplement and the accompanying prospectus may be made available in electronic format on websites or through other online services maintained by the placement agent, or by an affiliate. Other than this prospectus supplement and the accompanying prospectus in electronic format, the information on the placement agent’s websites and any information contained in any other website maintained by the placement agent is not part of this prospectus supplement and the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by investors.

Other

From time to time, the placement agent and its respective affiliates may in the future provide various investment banking, financial advisory and other services to us and our affiliates for which services they may receive customary fees. In the course of their businesses, the placement agent and its respective affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the placement agent and its respective affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, the placement agent has not provided any investment banking or other financial services during the 180-day period preceding the date of this prospectus supplement and we do not expect to retain the placement agent to perform any investment banking or other financial services for at least 90 days after the date of this prospectus supplement.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement and securities purchase agreement. A copy of the placement agency agreement and the form of securities purchase agreement with the investors will be included as exhibits to our Current Report on Form 8-K that will be filed with the SEC and incorporated by reference into the Registration Statement of which this prospectus supplement forms a part.

The transfer agent for our common stock to be issued in this offering is American Stock Transfer & Trust Company, LLC.

PRIVATE PLACEMENT OF COMMON WARRANTS

In a concurrent private placement, we are selling to each institutional investor in this offering Common Warrants to purchase one share of common stock for each share of common stock purchased in this offering by each such investor. The aggregate number of Common Warrant Shares exercisable pursuant to the Common Warrants is 800,000. The Common Warrants will be exercisable at an exercise price of \$2.85 per share. The exercise price and number of Common Warrant Shares issuable upon the exercise of the Common Warrants will be subject to adjustment in the event of any stock dividend and split, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Common Warrants.

Each Common Warrant shall be exercisable beginning six months after the date of issuance and have a term of exercise equal to five and one-half years from the date of issuance. A holder of Common Warrants will have the right to exercise the Common Warrants on a “cashless” basis in certain circumstances as described in the Common Warrants, including, among others, if at any time after the six-month anniversary of the closing date of this offering there is no effective registration statement registering the resale of the Common Warrant Shares. Subject to limited exceptions, a holder of Common Warrants will not have the right to exercise any portion of its Common Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise, provided that the holder may increase or decrease the beneficial ownership limitation up to 9.99%. Any increase in the beneficial ownership limitation shall not be effective until 61 days following notice of such change to the Company. In addition, in certain circumstances, upon a fundamental transaction, the holder will have the right to require us to repurchase its Common Warrants at the Black Scholes value; provided, however, that if the Fundamental Transaction is not within the Company’s control, including not approved by the Company’s Board of Directors, the holder shall not have the option to require the Company to purchase its Common Warrant.

The Common Warrants and the Common Warrant Shares are being offered pursuant to the exemptions provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder, and they are not being offered pursuant to this prospectus supplement and the accompanying prospectus. 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. All purchasers are required to be “accredited investors” as such term is defined in Rule 501(a) under the Securities Act.

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 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, 2021](#), have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, 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-3 under the Securities Act with respect to the securities being offered hereby. This prospectus supplement and the accompanying prospectus, which constitute a part of the registration statement, do 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 supplement and the accompanying 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 supplement and the accompanying 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 supplement and the accompanying prospectus, except for information incorporated by reference that is superseded by information contained in this prospectus supplement and the accompanying prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any statements in this prospectus supplement, the accompanying prospectus or any document previously incorporated by reference have been modified or superseded. This prospectus supplement 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, 2021](#);
- our Quarterly Reports on Form 10-Q for the quarters ended [March 31](#), and [June 30, 2022](#);
- our Current Reports on Form 8-K filed with the SEC on [February 18, 2022](#), [February 25, 2022](#) and [April 6, 2022](#) (other than information furnished under Item 7.01 and exhibits related thereto); and
- the description of our common stock contained in our registration statement on [Form 8-A filed with the SEC on March 5, 2014](#), 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 supplement or accompanying 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 after the date of this prospectus supplement and until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus supplement and accompanying 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 supplement and accompanying prospectus are 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 supplement or accompanying prospectus but not delivered with the prospectus supplement and accompanying 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



**\$110,000,000
COMMON STOCK
PREFERRED STOCK
WARRANTS
UNITS**

We may from time to time offer and sell up to \$110,000,000 of common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination of the foregoing, either individually or in units, at prices and on terms described in one or more supplements to this prospectus. We may also offer securities as may be issuable upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including any applicable anti-dilution provisions.

This prospectus provides the general terms of the securities we may offer and the general manner in which these securities will be offered. Each time we offer to sell securities, we will provide specific terms related to such offers in a supplement to this prospectus. The prospectus supplements may also add, update or change information contained in this prospectus. Before you invest, you should carefully read this prospectus and the applicable prospectus supplement, as well the documents incorporated by reference in this prospectus. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "BPTH." On May 20, 2022, the last reported sales price per share of our common stock on the Nasdaq Capital Market was \$3.13.

We will sell these securities directly, through agents, dealers or underwriters as designated from time to time, or through a combination of these methods. For additional information on the methods of sale, you should refer to the section titled "Plan of Distribution" in this prospectus. If any agents, dealers or underwriters are involved in the sale of these securities, the applicable prospectus supplement will set forth the names of the agents, dealers or underwriters and any applicable fees, commissions or discounts. The price to the public of such securities and the net proceeds that we expect to receive from such sale will also be set forth in a supplement to this prospectus.

As of May 27, 2022, the aggregate market value of our outstanding common stock held by non-affiliates was \$28,504,680, based on 7,160,164 shares of outstanding common stock, of which 7,126,170 shares are held by non-affiliates, and the last reported sale price of our common stock of \$4.00 per share on April 4, 2022. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75,000,000. We have not sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar month period that ends on and includes the date hereof.

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, the applicable prospectus supplement and the documents incorporated by reference in this prospectus and applicable prospectus supplement. See "Risk Factors" on page 5 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 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 June 14, 2022

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration statement process, we may from time to time sell common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination of the foregoing, either individually or in units, in one or more offerings up to an offering amount of \$110,000,000. This prospectus provides you with a general description of the securities we may offer and the general manner in which these securities will be offered.

Each time we offer securities hereunder, we will provide specific terms related to such offering in a supplement to this prospectus.

The prospectus supplements may add, update or change any of the information contained in this prospectus or in the documents that we have incorporated by reference into this prospectus. We urge you to read carefully this prospectus and the applicable prospectus supplement, together with the information incorporated herein by reference as described under the sections titled “Where You Can Find More Information” and “Information Incorporated by Reference” below. If there is any inconsistency between the information in this prospectus and any prospectus supplement, you should rely on the information contained in that prospectus supplement.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

You should rely only on the information we have provided or incorporated by reference in this prospectus and the applicable prospectus supplement. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or the applicable prospectus supplement. You must not rely on any unauthorized information or representation. This prospectus or any applicable supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus or any applicable supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should assume that the information in this prospectus is accurate only as of the date on the front of the 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 contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section titled “Where You Can Find More Information.”

Unless the context requires otherwise, references in this prospectus to “we,” “our,” “us,” “the Company” and “Bio-Path” refer to Bio-Path Holdings, Inc. and its wholly-owned subsidiary. Bio-Path Holdings, Inc.’s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as “Bio-Path Subsidiary.”

PROSPECTUS SUMMARY

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

Our Company

We are a clinical and preclinical stage oncology-focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target-specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNabilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating *in vivo*, incorporated inside of a 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 115 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 azacitidine (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.

Bio-Path's 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 preliminary 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 review performed after 19 evaluable patients. The study is anticipated to be conducted at 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 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 CR 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.

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 that will evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and CLL patients. The Phase 1 clinical trial is being conducted at several leading cancer centers, including MD Anderson Cancer Center and the Georgia Cancer Center. On November 19, 2020, we announced the enrollment and dosing of the first patient in the Phase 1 clinical trial.

Additionally, preclinical studies suggest that the combination of BP1002 with decitabine is efficacious in venetoclax-resistant 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 that will evaluate the ability of BP1002 to treat refractory/relapsed AML patients. The Phase 1/1b clinical trial is anticipated to be conducted at several leading cancer centers in the United States, including the Weill Medical College, MD Anderson Cancer Center and the Georgia Cancer Center. Gail J. Roboz, M.D., will serve as Principal Investigator for the Phase 1/1b 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 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 successfully completed several IND enabling studies of BP1003 in 2021 and expect to complete one additional IND enabling study in 2022. If that additional study is successfully completed, our goal is to file an IND in 2022. Based on the filing of the IND, we expect to 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, Bio-Path's 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. In late 2019, we filed an IND application to initiate a Phase 1/1b clinical trial of BP1001-A in patients with solid tumors, including ovarian, endometrial, pancreatic and breast cancer. Ovarian cancer is one of the most common types of gynecologic malignancies, with approximately 50% of all cases occurring in women older than 63 years. On October 27, 2021, we announced that the FDA cleared the IND application for BP1001-A for the initial Phase 1/1b clinical trial, which allows us to proceed with next steps to open the clinical trial.

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 nanoparticle antisense RNAi drug candidates. We have a new product identification template in place to define a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. As we expand 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.

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.

THE OFFERING

We may offer common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination of the foregoing, either individually or in units, in one or more offerings, with an aggregate initial offering price not to exceed \$110,000,000. This prospectus describes the general terms that may apply to the securities to be offered and the specific terms of any particular securities that we offer will be described in a separate supplement to this prospectus, including, to the extent applicable:

- designation or classification;
- aggregate offering price;
- ranking;
- rates and times of payment of dividends, if any;
- redemption, conversion, exchange or sinking fund terms, if any;
- restrictive covenants, if any;
- voting or other rights, if any;
- conversion, exchange and exercise prices, if any; and
- important federal income tax considerations.

We may offer and sell the securities directly, through agents, dealers or underwriters as designated from time to time, or through a combination of these methods. The applicable prospectus supplement will include any required information about the agents, dealers or underwriters we use and the applicable fees, commissions or discounts we may pay them for their services.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

RISK FACTORS

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

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.

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 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 and any applicable supplement to this prospectus, together with the information incorporated herein by reference as described under the section titled “Where You Can Find More Information,” completely and with the understanding that our actual future results may be materially different from what we expect. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Forward-looking statements include, but are not limited to, statements about:

- the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith;
- our lack of significant revenue to date, our history of recurring operating losses and our expectation of future operating losses;
- our need for substantial additional capital and our need to delay, reduce or eliminate our drug development and commercialization efforts if we are unable to raise additional capital;
- the highly-competitive nature of the pharmaceutical and biotechnology industry and our ability to compete effectively;
- the success of our plans to use collaboration arrangements to leverage our capabilities;
- our ability to retain and attract key personnel;
- the risk of misconduct of our employees, agents, consultants and commercial partners;
- disruptions to our operations due to expansions of our operations;
- the costs we would incur if we acquire or license technologies, resources or drug candidates;
- risks associated with product liability claims;
- our reliance on information technology systems and the liability or interruption associated with cyber-attacks or other breaches of our systems;
- our ability to use net operating loss carryforwards;
- provisions in our charter documents and state law that may prevent a change in control;
- work slowdown or stoppage at government agencies could negatively impact our business;
- our need to complete extensive clinical trials and the risk that we may not be able to demonstrate the safety and efficacy of our drug candidates;
- risks that 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, any applicable supplement to 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

Unless otherwise indicated in the applicable prospectus supplement, we expect to use the net proceeds from the sale of securities offered pursuant to this prospectus for working capital and general corporate purposes. Until the net proceeds are used for these purposes, we may deposit them in interest-bearing accounts or invest them in short-term marketable securities.

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 May 10, 2022, there were 7,160,164 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.

Preferred Stock

Our board of directors is authorized, without any further notice to or action of the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series. Our board of directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of our preferred stock, including without limitation authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. The board of directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in our certificate of incorporation or the resolution of our board of directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series. As of the date of this prospectus, no such shares had been designated.

The following briefly summarizes the material terms of preferred stock that we may offer, other than pricing and related terms disclosed in a prospectus supplement. You should read the particular terms of any series of preferred stock that we offer which we will describe in more detail in the applicable prospectus supplement relating to such series. You should also read the more detailed provisions of our certificate of incorporation and the statement with respect to shares relating to each particular series of preferred stock for provisions that may be important to you. The statement with respect to shares relating to each particular series of preferred stock offered by the applicable prospectus supplement and this prospectus will be filed as an exhibit to a document incorporated by reference in the prospectus. The prospectus supplement will also state whether any of the terms summarized below do not apply to the series of preferred stock being offered.

Rank. A series of preferred stock will have the rank set forth in the relevant certificate of designation and described in the prospectus supplement relating to the applicable series.

Voting Rights. The holders of shares of a series of preferred stock will have the voting rights provided by the applicable certificate of designation and as required by applicable law. These voting rights will be described in the relevant prospectus supplement.

Dividends. The certificate of designation setting forth the terms of a series of preferred stock may provide that the holders of that series are entitled to receive dividends, when, as and if authorized by our board of directors out of funds legally available for dividends, before any declaration or payment of any dividends on securities ranking junior to such series relating to dividends. The rates and dates of payment of dividends and any other terms applicable to the dividends will be set forth in the applicable certificate of designation and described in the prospectus supplement relating to the relevant series. To the extent provided in the certificate of designation, dividends will be payable to the holders of record of our preferred stock as they appear on our books on the record dates fixed by our board of directors. Dividends on any series of our preferred stock may be cumulative or noncumulative and payable in cash or in kind.

Conversion and Exchange. The certificate of designation setting forth the terms of a series of our preferred stock may provide for, and the prospectus supplement for the applicable series of preferred stock may describe, the terms, if any, on which shares of that series are convertible into or exchangeable for shares of our common stock or securities of a third party.

Redemption. If so specified in the certificate of designation setting forth the terms of a series of our preferred stock, which will be described in the applicable prospectus supplement, a series of our preferred stock may be redeemable at our or the holder's option and/or may be mandatorily redeemed partially or in whole.

Liquidation Preference. Upon any voluntary or involuntary liquidation, dissolution or winding up of our company, the holders of each series of our preferred stock may be entitled to receive distributions upon liquidation. Those distributions will be made before any distribution is made on any securities ranking junior to such series relating to liquidation. The terms and conditions of those distributions to the relevant series of our preferred stock will be set forth in the applicable certificate of designation and described in the relevant prospectus supplement.

Our board of directors may cause shares of preferred stock to be issued in public or private transactions for any proper corporate purposes, and such issuance could adversely affect the voting rights of the holders of our common stock. The issuance of our preferred stock could also affect the likelihood that the holders of common stock will receive dividends or distributions upon liquidation. In addition, the rights of the holders of the preferred stock offered may be adversely affected by the rights of the holders of any shares of our preferred stock that may be issued in the future. The preferred stock could have the effect of acting as an anti-takeover device to prevent a change in control of our company.

Unless the particular prospectus supplement states otherwise, the holders of each series of our preferred stock will not have any preemptive or subscription rights to acquire more of our capital stock.

The transfer agent, registrar, dividend disbursing agent and redemption agent for shares of each series of preferred stock will be named in the prospectus supplement relating to such series.

Limitation on Liability and Indemnification of Officers and Directors

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

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

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

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

- authorize our board of directors, without further action by the stockholders, to issue shares of preferred stock in one or more series, and with respect to each series, to fix the number of shares constituting that series and establish the rights and other terms of that series;
- establish advance notice procedures for stockholders to submit nominations of candidates for election to our board of directors and other proposals to be brought before a stockholders meeting;
- provide that our first amended and restated bylaws may be amended by our board of directors without stockholder approval;
- limit our stockholders' ability to call special meetings of stockholders;
- allow our directors to establish the size of the board of directors by action of the board, subject to a minimum of three members;
- provide that vacancies on our board of directors or newly created directorships resulting from an increase in the number of our directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- do not give the holders of our common stock cumulative voting rights with respect to the election of directors.

Business Combinations

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

- prior to the time that person became an interested stockholder, our board of directors approved either the business combination or the transaction which resulted in the person becoming an interested stockholder;
- upon consummation of the transaction which resulted in the person becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding certain shares; or
- at or subsequent to the time the person became an interested stockholder, the business combination is approved by the board of directors and by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, consolidation, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an interested stockholder is a person who, together with that person's affiliates and associates, owns, or within the previous three years owned, 15% or more of our voting stock. 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.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we include in the applicable prospectus supplement, summarizes the material terms and provisions of the warrants that we may offer under this prospectus. We may issue warrants for the purchase of shares of common stock and/or preferred stock. We may issue warrants independently or together with shares of common stock and/or shares of preferred stock, and the warrants may be attached to or separate from these securities. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below.

Before the issuance of a series of warrants, the form of warrant agreement, including a form of warrant certificate, if applicable, that describes the terms of the particular series of warrants we are offering will be filed as an exhibit to the registration statement of which this prospectus is a part, or incorporated by reference from reports that we file with the SEC. The following summaries of material provisions of the warrants are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the particular series of warrants that we may offer under this prospectus and the applicable prospectus supplement. We urge you to read the applicable prospectus supplements related to the particular series of warrants that we may offer under this prospectus, as well as any related free writing prospectuses, and the complete warrant agreements and warrant certificates that contain the terms of the warrants.

General

We will describe in the applicable prospectus supplement the terms of the warrants that may be offered, including the following, where applicable:

- the title of the warrants;
- the aggregate number of the warrants offered;
- the price or prices at which the warrants will be issued;
- the securities, which may include shares of any class or series of common stock or preferred stock, for which the warrants are exercisable;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the terms of any rights to redeem or call the warrants;
- the date on and after which the warrants and the related securities will be separately transferable;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to force the exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and the date on which the right will expire;
- the minimum or maximum number of warrants that may be exercised at any one time;
- the manner in which the warrant agreements and warrants may be modified;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- information relating to book-entry procedures;
- the listing of the warrants on a securities exchange or automated quotation system;
- whether the warrants may be sold separately or with other securities as parts of units;
- a discussion of material United States federal income tax considerations of holding or exercising the warrants; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Before exercising their warrants, the holders of warrants will not have any of the rights of the holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, the holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Unless we otherwise specify in the applicable prospectus supplement, the holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to us or to the warrant agent in immediately available funds, or, if provided in the applicable prospectus supplement, by cashless exercise. We will set forth in the warrant agreement, on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent in connection with the exercise of the warrant.

Unless we otherwise specify in the applicable prospectus supplement, upon receipt of the required exercise price and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we may issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, the holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Enforceability of Rights by Holders of Warrants

If we appoint a warrant agent, any such warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of any related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Warrant Adjustments

Unless the applicable prospectus supplement states otherwise, the exercise price of, and the number of securities covered by, a warrant to purchase shares of common stock or preferred stock will be adjusted proportionately if we subdivide or combine common stock or preferred stock, as applicable.

Warrant Agreement Will Not Be Qualified Under Trust Indenture Act

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

Currently Outstanding Warrants

As of May 25, 2022, we had issued and outstanding warrants to purchase 400,531 shares of our common stock with a weighted exercise price of \$15.39 per share.

DESCRIPTION OF UNITS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

Before the issuance of units, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, will be filed as an exhibit to the registration statement of which this prospectus is a part, or incorporated by reference from reports that we file with the SEC. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we sell under this prospectus, as well as any related free writing prospectuses, and the complete unit agreement and any supplemental agreements that contain the terms of the units.

General

We may issue units consisting of common stock, preferred stock and/or warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under “Description of Capital Stock” and “Description of Warrants” will apply to each unit and to any common stock, preferred stock and/or warrant included in each unit, respectively.

Issuance in Series

We may issue units in such amounts and in numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

If we appoint a unit agent, any such unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee, depositary or warrant or unit agent maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary’s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depositary or its participants. Consequently, for securities issued in global form, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a book-entry security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary’s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depositary will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depositary will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depositary participants or customers or by law, to pass it along to the indirect holders but does not do so.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consents, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a registered holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depository's rules and procedures will affect these matters.

Global Securities

A global security is a security that represents one or any other number of individual securities held by a depository. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depository for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee or a successor depository, unless special termination situations arise. We describe those situations below under the section titled "Special Situations When a Global Security Will Be Terminated" in this prospectus. As a result of these arrangements, the depository, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depository or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

The rights of an indirect holder relating to a global security will be governed by the account rules of the investor's financial institution and of the depository, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depository that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depository's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depository's actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depository in any way;
- the depository may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and
- financial institutions that participate in the depository's book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of the holders and street name investors above.

Unless we provide otherwise in the applicable prospectus supplement, the global security will terminate when the following special situations occur:

- if the depository notifies us that it is unwilling, unable or no longer qualified to continue as depository for that global security and we do not appoint another institution to act as depository within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The applicable prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the applicable prospectus supplement. When a global security terminates, the depository, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus from time to time in one or more offerings. Registration of the securities covered by this prospectus does not mean, however, that those securities will necessarily be offered or sold.

We may sell our securities, separately or together, in any one or more of the following ways:

- directly to investors, including through a specific bidding, auction or other process;
- to investors through agents;
- directly to agents;
- to or through brokers or dealers;
- to the public through underwriting syndicates led by one or more managing underwriters;
- in “at the market” offerings, within the meaning of Rule 415(a)(4) of the Securities Act or through a market maker or into an existing trading market on an exchange or otherwise;
- to one or more underwriters acting alone for resale to investors or to the public; and
- through any combination of the foregoing.

Sales of securities may be effected from time to time in one or more transactions, including negotiated transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to prevailing market prices; or
- at negotiated prices.

We will describe the method of distribution of the securities and the terms of the offering in the prospectus supplement. Any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters’ obligations to purchase the securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the securities if they purchase any of the securities. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivative transactions, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

We may grant underwriters who participate in the distribution of securities an option to purchase additional securities to cover over-allotments, if any, in connection with the distribution.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers, as their agents in connection with the sale of securities. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. The prospectus supplement will identify any such underwriter, dealer or agent and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

Unless otherwise specified in the related prospectus supplement, all securities we offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. Any common stock sold pursuant to a prospectus supplement will be listed on the Nasdaq Capital Market or other principal market for our common stock. We may apply to list any series of preferred stock or warrants on an exchange, but we are not obligated to do so. Therefore, there may not be liquidity or a trading market for any such series of preferred stock or such warrants.

Any underwriter may engage in over-allotment transactions, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. We make no representation or prediction as to the direction or magnitude of any effect that such transactions may have on the price of the securities. For a description of these activities, see the information under the section titled "Underwriting" or "Plan of Distribution" in the applicable prospectus supplement.

Underwriters, broker-dealers or agents who may become involved in the sale of the common stock may engage in transactions with and perform other services for us in the ordinary course of their business for which they receive compensation.

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Winstead PC, Houston, Texas. The validity of any securities will be passed upon for any underwriters or agents by counsel that we will name in the applicable prospectus supplement.

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, 2021](#), have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, 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 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, 2021](#);
- [our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022](#);
- our Current Reports on Form 8-K filed with the SEC on [February 18, 2022](#), [February 25, 2022](#) and [April 6, 2022](#) (other than information furnished under Item 7.01 and exhibits related thereto); and
- the description of our common stock contained in our registration statement on [Form 8-A filed with the SEC on March 5, 2014](#), 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 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 the offering of the securities made by this prospectus is terminated. 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



800,000 SHARES OF COMMON STOCK

PROSPECTUS SUPPLEMENT

Roth Capital Partners

November 6, 2022
