

PROSPECTUS



UP TO \$9,000,000 SHARES OF COMMON STOCK

This prospectus relates to the offer, issuance and sale from time to time of our common stock, par value \$0.001 per share, having an aggregate offering price of up to \$9,000,000 through H.C. Wainwright & Co., LLC, (“Wainwright”), as sales agent. These sales, if any, will be made pursuant to the terms of an At-The-Market Offering Agreement (the “Offering Agreement”), dated July 13, 2020, between us and Wainwright.

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.

Sales of our common stock, if any, under this prospectus may be made by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 of the Securities Act of 1933 (the “Securities Act”), including without limitation sales made directly on or through the Nasdaq Capital Market, the trading market for our common stock, or any other existing trading market in the United States for our common stock, sales made to or through a market maker other than on an exchange or otherwise, directly to Wainwright as principal in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or in any other method permitted by law. If we and Wainwright agree on a method of distribution other than sales of shares of our common stock into the Nasdaq Capital Market or another existing trading market at market prices, we will file a prospectus providing all information about such offering as required by Rule 424(b) under the Securities Act. Wainwright is not required to sell any certain number of shares or dollar amount of our common stock, but will act as a sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, subject to the terms of the Offering Agreement.

Wainwright will be entitled to compensation at a commission rate of 3.0% of the gross sales price per share sold. In connection with the sale of our common stock on our behalf, Wainwright will be deemed to be an “underwriter” within the meaning of the Securities Act, and the compensation of Wainwright will be deemed to be underwriting commissions or discounts. Please see “Plan of Distribution” on page 11 for further information relating to the compensation arrangements with Wainwright. We have also agreed to provide indemnification and contribution to Wainwright with respect to certain liabilities, including liabilities under the Securities Act or the Exchange Act of 1934, as amended (the “Exchange Act”).

There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

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 and the documents incorporated by reference in this prospectus. 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.

H.C. Wainwright & Co.

Prospectus dated June 14, 2022

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS	ii
PROSPECTUS SUMMARY	1
RISK FACTORS	5
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	7
USE OF PROCEEDS	9
DILUTION	10
PLAN OF DISTRIBUTION	11
DESCRIPTION OF CAPITAL STOCK	13
LEGAL MATTERS	15
EXPERTS	15
WHERE YOU CAN FIND MORE INFORMATION	15
INFORMATION INCORPORATED BY REFERENCE	15

ABOUT THIS PROSPECTUS

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

You should rely only on the information we have provided or incorporated by reference in this prospectus. If information in this prospectus is inconsistent with any document incorporated by reference filed prior to the date of this prospectus, you should rely on this prospectus; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date, 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. You must not rely on any unauthorized information or representation. You should assume that the information in this prospectus is accurate only as of the date hereof and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since those dates.

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

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

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus or in documents incorporated by reference. This summary does not contain all of the information that you should consider before making an investment decision. This prospectus include or incorporate by reference information about this offering, our business and our financial and operating data. You should carefully read the entire prospectus, including under the sections titled “Risk Factors” included therein, 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

Common stock offered by us	Shares of our common stock having an aggregate offering price of up to \$9,000,000.
Common stock to be outstanding immediately after this offering (1)	Up to 10,035,563 shares, assuming sales of 2,875,399 shares of our common stock in this offering at an offering price of \$3.13 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on May 20, 2022. The actual number of shares issued will vary depending on the sales price under this offering.
Plan of Distribution	Sales of our common stock, if any, under this prospectus may be made by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on the Nasdaq Capital Market, on any other existing trading market for the common stock in the United States. Wainwright is not required to sell any certain number of shares or dollar amount of our common stock, but will act as a sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, subject to the terms of the Offering Agreement. See “Plan of Distribution” on page 11.
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” on page 9.
Risk factors	An investment in our company involves a high degree of risk. Please refer to the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and other information included or incorporated by reference in this prospectus for a discussion of factors you should carefully consider before investing our securities.
Nasdaq Capital Market Symbol	“BPTH”
(1)	<p>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 March 31, 2022, which excludes as of such date:</p> <ul style="list-style-type: none">• 675,741 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 \$11.52 per share;• 391 additional shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan; and• 423,390 shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of \$20.98 per share.

RISK FACTORS

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

Any of these risks could have a material adverse effect on our business, prospects, financial condition and results of operations. In any such case, the trading price of our securities could decline and you could lose all or part of your investment. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations.

Additional Risks Related to This Offering

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

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

The common stock offered hereby will be sold in “at-the-market” offerings, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares in this offering at different times will likely pay different prices. As a result, investors may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience a decline in the value of their shares as a result of share sales made at prices lower than the prices they paid.

The actual number of shares of common stock we will issue under the Offering Agreement, at any one time or in total, is uncertain.

Subject to certain limitations in the Offering Agreement and compliance with applicable law, we have the discretion to deliver a sales notice to Wainwright as our sales agent at any time throughout the term of the Offering Agreement. The number of shares that are sold by Wainwright after delivering a sales notice will fluctuate based on the market price of our common stock during the sales period and limits we set with Wainwright. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on an assumed offering price of \$3.13 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on May 20, 2022, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately \$0.07 per share in the net tangible book value of the common stock. See the section titled “Dilution” in this prospectus for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering. In addition, we have a significant number of stock options and warrants outstanding. To the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution.

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

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 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

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

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

DILUTION

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

Our net tangible book value per share is determined by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. The historical net tangible book value of our common stock as of March 31, 2022 was approximately \$22.0 million, or \$3.08 per share, based on 7,160,164 shares of common stock outstanding at March 31, 2022.

After giving effect to our sale in this offering of shares of our common stock in the aggregate amount of \$9,000,000 at an assumed public offering price of \$3.13 per share (the last reported sale price of our common stock on the Nasdaq Capital Market on May 20, 2022), and after deducting the sales agent commissions and our estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2022 would have been approximately \$30.7 million, or \$3.06 per share of common stock. This represents an immediate decrease in net tangible book value of \$0.02 per share to existing stockholders and an immediate dilution of \$0.07 per share to new investors purchasing shares of common stock in this offering at the assumed public offering price. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		\$	3.13
Historical net tangible book value per share as of March 31, 2022	\$	3.08	
Decrease in net tangible book value per share attributable to new investors	\$	(0.02)	
As adjusted net tangible book value per share after this offering		\$	3.06
Dilution per share to new investors		\$	0.07

The table above assumes for illustrative purposes that an aggregate of 2,875,399 shares of our common stock are sold at a price of \$3.13 per share, the last reported sale price of our common stock on the Nasdaq Capital Market on May 20, 2022, for aggregate gross proceeds of approximately \$9,000,000. The shares sold in this offering, if any, will be sold from time to time at various prices. An increase of \$1.00 per share in the price at which the shares are sold from the assumed public offering price of \$3.13 per share shown in the table above, assuming all of our common stock in the aggregate amount of approximately \$9,000,000 is sold at that price, would increase the dilution in net tangible book value per share to new investors in this offering to \$0.84 per share, after deducting commissions and estimated offering expenses payable by us. A decrease of \$1.00 per share in the price at which the shares are sold from the assumed public offering price of \$3.13 per share shown in the table above, assuming all of our common stock in the aggregate amount of approximately \$9,000,000 is sold at that price, would not result in dilution in net tangible book value per share to new investors in this offering, after deducting commissions and estimated offering expenses payable by us. This information is supplied for illustrative purposes only.

The above discussion and table are based on 7,160,164 shares of our common stock outstanding as of March 31, 2022, which excludes as of such date:

- 675,741 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 \$11.52 per share;
- 391 additional shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan; and
- 423,390 shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of \$20.98 per share.

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

PLAN OF DISTRIBUTION

We previously entered into the Offering Agreement with Wainwright, dated July 13, 2020, under which, and pursuant to this prospectus, we may issue and sell from time to time shares of our common stock having an aggregate offering price of not more than \$9,000,000 through Wainwright as our sales agent. Sales of the common stock, if any, will be made by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415 promulgated under the Securities Act. If we and Wainwright agree on any method of distribution other than sales of shares of our common stock into the Nasdaq Capital Market or another existing trading market in the United States at market prices, we will file a prospectus supplement providing all information about such offering as required by Rule 424(b) under the Securities Act.

Wainwright will offer our common stock at prevailing market prices subject to the terms and conditions of the Offering Agreement as agreed upon by us and Wainwright. We will designate the number of shares which we desire to sell, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in one day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Offering Agreement, Wainwright will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell on our behalf all of the shares of common stock requested to be sold by us. We or Wainwright may suspend the offering of the common stock being made through Wainwright under the Offering Agreement upon proper notice to the other party.

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

We will pay Wainwright in cash, upon each sale of our shares of common stock pursuant to the Offering Agreement, a commission equal to 3.0% of the gross proceeds from each sale of shares of our common stock. Because there is no minimum offering amount required as a condition to this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. Pursuant to the terms of the Offering Agreement, we agreed to reimburse Wainwright for the reasonable fees and expenses of its legal counsel incurred in connection with entering into the transactions contemplated by the Offering Agreement in an amount not to exceed \$50,000 in the aggregate. Additionally, pursuant to the terms of the Offering Agreement, we agreed to reimburse Wainwright for the documented fees and costs of its legal counsel reasonably incurred in connection with Wainwright’s ongoing diligence, drafting and other filing requirements arising from the transactions contemplated by the Offering Agreement in an amount not to exceed \$2,500 in the aggregate per calendar quarter. We will disclose in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, the number of shares of our common stock sold through Wainwright under the Offering Agreement, the net proceeds to us and the compensation paid by us with respect to sales under the Offering Agreement during the relevant quarter.

In connection with the sales of common stock on our behalf, Wainwright will be deemed to be an “underwriter” within the meaning of the Securities Act, and the compensation paid to Wainwright will be deemed to be underwriting commissions or discounts. We have agreed in the Offering Agreement to provide indemnification and contribution to Wainwright against certain liabilities, including liabilities under the Securities Act.

The offering of our shares of common stock pursuant to the Offering Agreement and this prospectus will terminate upon the earlier of the (i) sale of all of our shares of common stock provided for in this prospectus or (ii) termination of the Offering Agreement as permitted therein.

To the extent required by Regulation M, Wainwright will not engage in any market making activities involving our shares of common stock while the offering is ongoing under this prospectus.

We have already paid Wainwright an aggregate of \$254,506 in commissions pursuant to the Offering Agreement through the date of this prospectus. From time to time, Wainwright may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. Wainwright served as our exclusive placement agent in connection with our registered direct offerings we consummated in July 2016, September 2018, January 2019, including a concurrent private placement in January 2019, March 2019, and November 2019, and as the underwriter in connection with our underwritten public offering that we consummated on January 17, 2019, and Wainwright received compensation for each such offering. However, except as disclosed in this prospectus, we have no present arrangements with Wainwright for any further services.

This summary of the material provisions of the Offering Agreement does not purport to be a complete statement of its terms and conditions. We previously filed a copy of the Offering Agreement as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on July 14, 2020.

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

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

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 and to determine the relative rights, preferences and privileges of the shares of any such series.

Limitation on Liability and Indemnification of Officers and Directors

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

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

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

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

- authorize our board of directors, without further action by the stockholders, to issue shares of preferred stock in one or more series, and with respect to each series, to fix the number of shares constituting that series and establish the rights and other terms of that series;
- establish advance notice procedures for stockholders to submit nominations of candidates for election to our board of directors and other proposals to be brought before a stockholders meeting;
- provide that our first amended and restated bylaws may be amended by our board of directors without stockholder approval;
- limit our stockholders’ ability to call special meetings of stockholders;

- allow our directors to establish the size of the board of directors by action of the board, subject to a minimum of three members;
- provide that vacancies on our board of directors or newly created directorships resulting from an increase in the number of our directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- do not give the holders of our common stock cumulative voting rights with respect to the election of directors.

Business Combinations

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

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

Generally, a business combination includes a merger, consolidation, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an interested stockholder is a person who, together with that person’s affiliates and associates, owns, or within the previous three years owned, 15% or more of our voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us.

Listing

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

Transfer Agent and Registrar

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

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Winstead PC, Houston, Texas. Certain legal matters will be passed upon for Wainwright by Sichenzia Ross Ference LLP, New York, New York.

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



UP TO \$9,000,000 SHARES OF COMMON STOCK

H.C. Wainwright & Co.

June 14, 2022
