As filed with the Securities and Exchange Commission on May 27, 2022

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**4710 Bellaire Boulevard, Suite 210** **Bellaire, Texas 77401** **(832) 742-1357**	**87-0652870**
(State or other jurisdiction of incorporation or organization)	(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)	(I.R.S. Employer Identification Number)

Peter H. Nielsen
President and Chief Executive Officer
4710 Bellaire Boulevard, Suite 210
Bellaire, Texas 77401
(832) 742-1357

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies To:
William R. Rohrlich, II
Winstead PC
600 Travis Street
Suite 5200
Houston, Texas 77002
Tel. (281) 681-5912
Fax (281) 681-5901

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box: ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

Explanatory Note

This registration statement contains three prospectuses:

- a base prospectus covering the offering, issuance and sale of such indeterminate number of shares of common stock and preferred stock, such indeterminate number of warrants to purchase common stock and preferred stock and such indeterminate number of units as shall have an aggregate initial offering price not to exceed $110,000,000;

- an at-the-market prospectus covering the offering, issuance and sale of shares of our common stock with an aggregate offering price of up to $9,000,000 that may be issued and sold under the At-The-Market Offering Agreement we entered into with H.C. Wainwright & Co., LLC on July 13, 2020 (the "Offering Agreement"); and

- a warrant exercise prospectus covering the offering, issuance and sale of 237,890 shares of our common stock pursuant to the exercise of warrants to purchase shares of our common stock outstanding on May 27, 2022.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus will be specified in a prospectus supplement to the base prospectus. The at-the-market agreement prospectus immediately follows the base prospectus. The common stock that may be offered, issued and sold under the at-the-market agreement prospectus is included in the $110,000,000 of securities that may be offered, issued and sold by us under the base prospectus. Upon termination of the Offering Agreement with H.C. Wainwright & Co., LLC, any portion of the $9,000,000 included in the at-the-market agreement prospectus that is not sold pursuant to the Offering Agreement will be available for sale in other offerings pursuant to the base prospectus and a corresponding prospectus supplement. The warrant exercise prospectus immediately follows the at-the-market agreement prospectus. The shares of our common stock that may be issued pursuant to the warrant exercise prospectus are not included in the $110,000,000 of securities that may be offered, issued and sold by us under the base prospectus.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 27, 2022

PROSPECTUS

$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 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. 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 , 2022

TABLE OF CONTENTS

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 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.

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 depositary'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 depositary. 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 depositary. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depositary 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 depositary, its nominee or a successor depositary, 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 depositary, 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 depositary 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 depositary, 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 depositary 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 depositary'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 depositary's actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depositary in any way;
- the depositary 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 depositary'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 depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary 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 depositary, 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

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 27, 2022

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 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. 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 , 2022

TABLE OF CONTENTS

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 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.

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) 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:

- 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

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 27, 2022

PROSPECTUS

237,890 Shares of Common Stock

This prospectus relates to the issuance by us of up to 237,890 shares of our common stock, par value $0.001 per share, issuable upon the exercise of outstanding warrants. Of these shares:

- 189,405 shares of our common stock are issuable upon the exercise of warrants exercisable at an exercise price of $9.90 per share (the "2019 Investor Warrants") that were originally issued by us on November 25, 2019, pursuant to a prospectus dated June 5, 2019, and a related prospectus supplement dated November 21, 2019; and
- 48,485 shares of our common stock are issuable upon the exercise of warrants exercisable at an exercise price of $12.375 per share (the "2019 Agent Warrants" and together with the 2019 Investor Warrants, the "Warrants") that were originally issued by us on November 25, 2019, pursuant to a prospectus dated June 5, 2019, and a related prospectus supplement dated November 21, 2019.

Each 2019 Investor Warrant is exercisable at any time after November 25, 2019 until its expiration date, which date is five years from November 25, 2019.

Each 2019 Agent Warrant is exercisable at any time after November 25, 2019 until its expiration date, which date is five years from November 21, 2019.

We will receive the proceeds from the exercise of the Warrants, but not from the sale of the underlying shares of common stock.

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. The Warrants are not listed, and we do not intend to apply to list them, on the Nasdaq Capital Market or any other national securities exchange.

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 4 of this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2022.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus relates to the offering of our common stock issuable upon the exercise of the outstanding Warrants. 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. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representation. You should assume that the information in this prospectus is accurate only as of the dates on the front of this document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since those dates.

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

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

PROSPECTUS SUMMARY

This prospectus summary highlights selected information contained elsewhere in this prospectus or in documents incorporated by reference. This summary does not contain all of the information that you should consider before making an investment decision. You should carefully read the entire prospectus, 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 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.

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	237,890 shares of our common stock, par value $0.001 per share, (i) 189,405 of which are issuable at an exercise price of $9.90 per share upon the exercise of the 2019 Investor Warrants that were originally issued by us on November 25, 2019, pursuant to a prospectus dated June 5, 2019, and a related prospectus supplement dated November 21, 2019; and (ii) 48,485 of which are issuable at an exercise price of $12.375 per share upon the exercise of the 2019 Agent Warrants that were originally issued by us on November 25, 2019, pursuant to a prospectus dated June 5, 2019, and a related prospectus supplement dated November 21, 2019.
Common stock to be outstanding immediately after this offering (1)	7,398,054 shares (assuming the exercise of all Warrants).
Use of proceeds	We currently expect to use the net proceeds from this offering, if any, for working capital and general corporate purposes. See "Use of Proceeds" on page 8.
NASDAQ Capital Market symbol	"BPTH"
Risk factors	An investment in our company involves a high degree of risk. Please refer to the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and other information included or incorporated by reference in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

(1) The number of shares of common stock to be outstanding after this offering is based on 7,160,164 shares of 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 the Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (the "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.

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

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 pursuant to the exercise of the Warrants. Assuming that all 237,890 shares of our common stock are sold in this offering upon the exercise of the Warrants, you will suffer immediate and substantial dilution of approximately $7.09 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 pursuant to the exercise of the Warrants.

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

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 purchase shares of our common stock upon the exercise of your Warrant, you will experience immediate and substantial dilution to the extent of the difference between the exercise price per share 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 of 237,890 shares of common stock issuable upon the exercise of the 2019 Investor Warrants and the 2019 Agent Warrants at a weighted exercise price of $10.41 per share, our net tangible book value as of March 31, 2022 would have been approximately $24.5 million, or $3.32 per share of common stock. This represents an immediate increase in net tangible book value of $0.24 per share to existing stockholders and an immediate dilution of $7.09 per share to new investors in this offering. The following table illustrates this dilution on a per share basis:

Weighted average exercise price per share			$	10.41
Historical net tangible book value per share as of March 31, 2022	$	3.08		
Increase in net tangible book value per share attributable to this offering	$	0.24		
As adjusted net tangible book value per share after this offering			$	3.32
Dilution per share to investors in this offering upon exercise of the Warrants			$	7.09

The above discussion and table are based on the weighted average exercise price of the Warrants and on 7,160,164 shares of 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 the 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, other than the Warrants. To the extent that any of these outstanding warrants or options are exercised or we issue additional shares under our equity incentive plans, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

PLAN OF DISTRIBUTION

The common stock referenced on the cover page of this prospectus will be offered solely by us and will be issued and sold upon the exercise of the Warrants described herein. For the holders of Warrants to exercise the Warrants, the shares issuable upon exercise must either be registered under the Securities Act or exempt from registration. If a registration statement registering the issuance of the shares of common stock underlying the Warrants under the Securities Act is not effective or available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Warrant. No fractional shares of common stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, we will, at our discretion, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

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.

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

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth an estimate of the fees and expenses payable by the registrant in connection with the issuance and distribution of the securities being registered. All amounts are estimated except the SEC registration fee. All of the expenses below will be paid by us.

	AMOUNT
SEC registration fee	$ 1,392
Printing and related expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* The amount of securities and the number of offerings are indeterminable and the expenses cannot be estimated at this time.

Item 15. Indemnification of Directors and Officers.

Section 102(b)(7) of the Delaware General Corporation Law (the "DGCL") permits a corporation to eliminate or limit the personal liability of its directors to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that to the fullest extent elimination or limitation of personal liability of directors is permitted by the DGCL, no director of the Company shall be liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director.

Section 145 of the DGCL permits a corporation to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is party or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our first amended and restated bylaws and our certificate of incorporation provide that each person (and the heirs, executors or administrators of such person) who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was a director or officer of the Company shall be indemnified and held harmless by the Company to the fullest extent permitted by applicable law. Our certificate of incorporation also states that we will pay or reimburse the reasonable expenses incurred in defending any such action, suit or proceeding in advance of its final disposition if we have received an undertaking by the person receiving such payment or reimbursement to repay all amounts advanced if it should be ultimately determined that he or she is not entitled to be indemnified.

We have entered into indemnification agreements with each of our directors. The contractual rights to indemnification provided by these indemnity agreements are subject to the limitations and conditions specified in such agreements.

The effect of the foregoing is to require us to indemnify our officers and directors for any claim arising against such persons in their official capacities if such person acted in good faith and in a manner that he or she reasonably believed to be in or not contrary to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors and officers, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

We have directors and officers insurance which includes insurance for claims against these persons brought under securities laws.

Item 16. Exhibits.

The following documents are filed as exhibits to this registration statement:

Exhibit Number	Exhibit
1.1*	Form of Underwriting Agreement.
1.2	At-the-Market Offering Agreement, by and between the Company and H.C. Wainwright & Co., LLC, dated July 13, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 14, 2020).
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.2	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2018).
3.3	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
3.4	First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 7, 2017).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K filed on March 16, 2015).
4.2	Form of Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 22, 2019).
4.3	Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 22, 2019).
4.4*	Specimen Preferred Stock Certificate and Form of Certificate of Designation of Preferred Stock.
4.5*	Form of Common Stock Warrant Agreement and Common Stock Warrant Certificate.
4.6*	Form of Preferred Stock Warrant Agreement and Preferred Stock Warrant Certificate.
4.7*	Form of Unit Agreement.
5.1+	Opinion of Winstead PC.
23.1+	Consent of Ernst & Young LLP
23.2+	Consent of Winstead PC (included in Exhibit 5.1).
24.1+	Powers of Attorney (included in Signature Page).
107	Filing Fee Table

* To be filed by amendment hereto or as an exhibit to a report filed pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, and incorporated herein by reference, if applicable.
+ Filed herewith

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of a prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the undersigned registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registration pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bellaire, State of Texas, on May 27, 2022.

BIO-PATH HOLDINGS, INC.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter H. Nielsen his or her true and lawful attorney-in-fact, with the power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including pre-effective amendments and post-effective amendments) to this registration statement, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

/s/ Peter H. Nielsen Peter H. Nielsen President, Chief Executive Officer (Principal Executive Officer), Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) and Director	May 27, 2022
/s/ Heath W. Cleaver Heath W. Cleaver Director	May 27, 2022
/s/ Paul D. Aubert Paul D. Aubert Director	May 27, 2022
/s/ Aline Sherwood Aline Sherwood Director	May 27, 2022
/s/ Douglas P. Morris Douglas P. Morris Director and Secretary	May 27, 2022

May 27, 2022

Bio-Path Holdings, Inc.
4710 Bellaire Boulevard, Suite 210
Bellaire, Texas 77401

Ladies and Gentlemen:

We have acted as counsel to Bio-Path Holdings, Inc., a Delaware corporation (the "Company"), in connection with the filing with the Securities and Exchange Commission (the "SEC") of a registration statement on Form S-3 (the "Registration Statement") under the Securities Act of 1933, as amended (the "Securities Act"), including a base prospectus (the "Base Prospectus"), which provides that it will be supplemented in the future by one or more prospectus supplements (each, a "Prospectus Supplement"), relating to the registration of the Company's:

(i) common stock, $0.001 par value per share ("Common Stock");

(ii) preferred stock, $0.001 par value per share ("Preferred Stock");

(iii) warrants to purchase shares of Common Stock and Preferred Stock ("Warrants"); and

(iv) units comprised of one or more shares of Common Stock, shares of Preferred Stock or Warrants in any combination ("Units," and together with the Common Stock, the Preferred Stock and the Warrants, the "Shelf Securities");

all of which may be issued from time to time on a delayed or continuous basis pursuant to Rule 415 under the Securities Act at an aggregate offering price not to exceed $110,000,000.

We have also acted as counsel to the Company in connection with the offering, issuance and sale of shares of Common Stock having an aggregate offering price of up to $9,000,000 (the "Offering Agreement Shares") under an At-The-Market Offering Agreement dated as of June 24, 2015 (the "Offering Agreement"). The prospectus for the offer and sale of the Offering Agreement Shares is included in the Registration Statement (as may be amended or supplemented, the "Offering Agreement Prospectus").

We have also acted as counsel to the Company in connection with the offer, sale and issuance of up to 189,405 shares of Common Stock (the "2019 Investor Warrant Shares") pursuant to the exercise of currently outstanding warrants that were originally issued on November 25, 2019 (the "2019 Investor Warrants"), and the offer, sale and issuance of up to 48,485 shares of Common Stock (the "2019 Agent Warrant Shares" and together with the 2019 Investor Warrant Shares, the "Warrant Shares") pursuant to the exercise of currently outstanding warrants that were originally issued on November 25, 2019 (the "2019 Agent Warrants" and together with the 2019 Investor Warrants, the "Outstanding Warrants"). The prospectus for the offer and sale of the Warrant Shares is included in the Registration Statement (as may be amended or supplemented, the "Warrant Exercise Prospectus").

The Shelf Securities, the Offering Agreement Shares and the Warrant Shares are collectively referred to herein as the "Securities."

In connection with this opinion, we have examined originals or copies, certified or otherwise identified to our satisfaction, of (i) the Registration Statement, (ii) the Base Prospectus; (iii) the Offering Agreement Prospectus; (iv) the Warrant Exercise Prospectus; (v) the Offering Agreement; (vi) the Outstanding Warrants; (vii) the Certificate of Incorporation of the Company, as currently in effect; (viii) the First Amended and Restated Bylaws of the Company, as currently in effect; (ix) certain resolutions adopted by the Board of Directors of the Company and (x) such other records, certificates and documents as we have deemed appropriate or necessary for the purposes of this opinion. We have also examined originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates of public officials, certificates of officers or other representatives of the Company and others, and such other documents, certificates and records, as we have deemed necessary or appropriate as a basis for the opinions set forth herein.

In our examination, we have assumed and have not verified (i) the legal capacity of all natural persons; (ii) the genuineness of all signatures; (iii) the authenticity of all documents submitted to us as originals; (iv) the conformity with the originals of all documents supplied to us as copies; (v) the accuracy and completeness of all corporate records and documents made available to us by the Company and (vi) that the foregoing documents, in the form submitted to us for our review, have not been altered or amended in any respect material to our opinions stated herein. We have relied as to factual matters upon certificates from officers of the Company and certificates and other documents from public officials and government agencies and departments and we have assumed the accuracy and authenticity of such certificates and documents.

With respect to our opinions as to the Securities, we have also assumed that (i) the Registration Statement, and any amendments thereto (including post-effective amendments), will have become effective and will comply with all applicable laws; (ii) all Securities will be issued and sold in compliance with applicable federal and state securities laws and in the manner stated in the Registration Statement and any applicable Prospectus Supplement; and (iii) with respect to shares of Common Stock or Preferred Stock offered, there will be sufficient shares of Common Stock or Preferred Stock authorized under the Company's Certificate of Incorporation and not otherwise reserved for issuance.

With respect to our opinions as to the Shelf Securities, we have also assumed that (i) a Prospectus Supplement, if required, will have been delivered and filed with the SEC describing the Shelf Securities offered thereby; (ii) a definitive purchase, underwriting or similar agreement with respect to any Shelf Securities offered will have been duly authorized and validly executed and delivered by the Company and the other parties thereto and will have been filed either as an exhibit to an amendment to the Registration Statement or incorporated by reference therein; (iii) any Shelf Securities issuable upon conversion, exchange or exercise of any Shelf Security being offered will have been duly authorized, created and, if appropriate, reserved for issuance upon such conversion, exchange or exercise; and (iv) any warrant agreement relating to the Warrants or unit agreement relating to the Units will, in each case, be governed by and construed in accordance with the laws of the State of New York and will constitute a valid and binding obligation of each party thereto other than the Company.

Based on the foregoing and subject to the limitations, qualifications and assumptions set forth herein, we are of the opinion that:

1. All requisite action necessary to make any shares of Common Stock (other than the Offering Agreement Shares and the Warrant Shares) validly issued, fully paid and nonassessable will have been taken when:

a. The Company's Board of Directors, or a committee thereof duly authorized by the Board of Directors, has adopted appropriate resolutions to authorize the issuance and sale of the Common Stock;

b. The terms of such Common Stock and of its issuance and sale have been established so as not to violate the Certificate of Incorporation or First Amended and Restated Bylaws of the Company or any applicable law or result in a default under or breach of any agreement or instrument binding upon the Company and so as to comply with any requirements or restrictions imposed by any court or governmental entity having jurisdiction over the Company; and

c. Such shares of Common Stock have been issued and sold for the consideration contemplated by, and otherwise in conformity with, the Registration Statement, as supplemented by a Prospectus Supplement with respect to such issuance and sale, and the acts, proceedings and documents referred to above.

2. All requisite action necessary to make any shares of Preferred Stock validly issued, fully paid and nonassessable will have taken place when:

a. The Company's Board of Directors, or a committee thereof duly authorized by the Board of Directors, has adopted appropriate resolutions to establish the powers, designations, preferences and relative participating, optional or other rights, if any, or the qualifications, limitations or restrictions, if any, and other terms of such shares of Preferred Stock as set forth in or contemplated by the Registration Statement, the exhibits thereto and any Prospectus Supplement relating to the Preferred Stock, and to authorize the issuance and sale of such shares of Preferred Stock;

b. A Certificate of Designations with respect to the powers, designations, preferences and relative participating, optional or other rights, if any, or the qualifications, limitations or restrictions, if any, and other terms of such shares of Preferred Stock has been filed with the Secretary of State of the State of Delaware in the form and manner required by law;

c. The terms of such Preferred Stock and of its issuance and sale have been established so as not to violate the Certificate of Incorporation or First Amended and Restated Bylaws of the Company or any applicable law or result in a default under or breach of any agreement or instrument binding upon the Company and so as to comply with any requirements or restrictions imposed by any court or governmental entity having jurisdiction over the Company; and

d. Such shares of Preferred Stock have been issued and sold for the consideration contemplated by, and otherwise in conformity with, the Registration Statement, as supplemented by a Prospectus Supplement with respect to such issuance and sale, and the acts, proceedings and documents referred to above.

3. All requisite action necessary to make any Warrants valid, legal and binding obligations of the Company, subject to (i) bankruptcy, insolvency, reorganization, fraudulent transfer, fraudulent conveyance, moratorium and other similar laws of general application affecting the rights and remedies of creditors and (ii) general principles of equity, regardless of whether applied in a proceeding in equity or at law, will have been taken when:

a. The Company's Board of Directors, or a committee thereof or one or more officers of the Company, in each case duly authorized by the Board of Directors, has taken action to approve and establish the terms and form of the Warrants and the documents, including any warrant agreements, evidencing and used in connection with the issuance and sale of the Warrants, and to authorize the issuance and sale of such Warrants;

b. The terms of such Warrants and of their issuance and sale have been established so as not to violate the Certificate of Incorporation or First Amended and Restated Bylaws of the Company or any applicable law or result in a default under or breach of any agreement or instrument binding upon the Company and so as to comply with any requirements or restrictions imposed by any court or governmental entity having jurisdiction over the Company;

c. Any such warrant agreements have been duly executed and delivered by the parties thereto;

d. Such Warrants have been duly executed and delivered in accordance with the terms and provisions of the applicable warrant agreement; and

e. Such Warrants have been issued and sold for the consideration contemplated by, and otherwise in conformity with, the Registration Statement, as supplemented by a Prospectus Supplement with respect to such issuance and sale, and the acts, proceedings and documents referred to above.

4. All requisite action necessary to make any Units valid, legal and binding obligations of the Company, subject to (i) bankruptcy, insolvency, reorganization, fraudulent transfer, fraudulent conveyance, moratorium and other similar laws of general application affecting the rights and remedies of creditors and (ii) general principles of equity, regardless of whether applied in a proceeding in equity or at law, will have been taken when:

a. The Company's Board of Directors, or a committee thereof or one or more officers of the Company, in each case duly authorized by the Board of Directors, has taken action to approve and establish the terms and form of the Units and the documents, including any unit agreements, evidencing and used in connection with the issuance and sale of the Units, and to authorize the issuance and sale of such Units;

b. The terms of such Units and of their issuance and sale have been established so as not to violate the Certificate of Incorporation or First Amended and Restated Bylaws of the Company or any applicable law or result in a default under or breach of any agreement or instrument binding upon the Company and so as to comply with any requirements or restrictions imposed by any court or governmental entity having jurisdiction over the Company;

c. Any such unit agreements have been duly executed and delivered by the parties thereto;

d. Such Units have been duly executed and delivered in accordance with the terms and provisions of the applicable unit agreement; and

e. Such Units have been issued and sold for the consideration contemplated by, and otherwise in conformity with, the Registration Statement, as supplemented by a Prospectus Supplement with respect to such issuance and sale, and the acts, proceedings and documents referred to above.

5. With respect to the Offering Agreement Shares, the Offering Agreement Shares have been duly authorized for issuance, and when issued and delivered by the Company and paid for pursuant to the terms of the Offering Agreement, the Offering Agreement Shares will be validly issued, fully paid and nonassessable.

6. With respect to the Warrant Shares, the Warrant Shares have been duly authorized and, upon the valid exercise in accordance with the terms of the 2019 Investor Warrants and the 2019 Agent Warrants, as applicable, and payment of the consideration required in connection therewith, the Warrant Shares will be validly issued, fully paid and non-assessable.

Our opinions herein are expressed solely as to the Delaware General Corporation Law (including, to the extent applicable, Delaware statutory and constitutional provisions and reported judicial decisions interpreting these laws), the laws of the United States and, as to the Warrants and the Units constituting valid, legal and binding obligations of the Company, solely with respect to the laws of the State of New York and the Delaware General Corporation Law. We express no opinion as to the laws of any other jurisdiction. The opinion expressed herein is given as of this date, and we do not undertake to supplement this opinion with respect to any events or changes occurring subsequent to the date of this letter. The opinion expressed in this letter is provided as a legal opinion only and not as any guarantee or warranty of the matters discussed herein, and such opinion is strictly limited to the matters stated herein, and no other opinion may be implied therefrom.

We hereby consent to the reference to our firm under the heading "Legal Matters" in the Base Prospectus, the Offering Agreement Prospectus and the Warrant Exercise Prospectus and to the filing of this opinion as an exhibit to the Registration Statement. In giving this consent, we do not admit that we are "experts" within the meaning of Section 11 of the Securities Act or within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the SEC promulgated thereunder.

Very truly yours,

/s/ Winstead PC

Winstead PC

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in this Registration Statement (Form S-3) and related Prospectus of Bio-Path Holdings, Inc. for the registration of common stock, preferred stock, warrants and units and to the incorporation by reference therein of our report dated March 10, 2022, with respect to the consolidated financial statements of Bio-Path Holdings, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2021, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Houston, Texas
May 27, 2022

Exhibit 107

Calculation of Filing Fee Tables

Form S-3
(Form Type)

Bio-Path Holdings, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees to Be Paid	Equity	Common Stock, par value $0.001 per share	—	—	—	—	—	—				
Fees to Be Paid	Equity	Preferred Stock, par value $0.001 per share	—	—	—	—	—	—				
Fees to Be Paid	Other	Warrants	—	—	—	—	—	—				
Fees to Be Paid	Other	Units	—	—	—	—	—	—				
Fees to Be Paid	Unallocated (Universal) Shelf	Unallocated (Universal) Shelf	457(o)	—	—	$ 15,007,311	0.0000927	$ 1,392				
Fees Previously Paid	—	—	—	—	—	—	—	—	—	—	—	—
Carry Forward Securities												
Carry Forward Securities	Equity	Common Stock, par value $0.001 per share	415(a)(6)									
Carry Forward Securities	Equity	Preferred Stock, par value $0.001 per share	415(a)(6)									
Carry Forward Securities	Other	Warrants	415(a)(6)									
Carry Forward Securities	Other	Units	415(a)(6)									
Carry Forward Securities	Unallocated (Universal) Shelf	Unallocated (Universal) Shelf	415(a)(6)			$ 94,992,689	0.0001212		S-3	333-231537	5-Jun-19	$ 11,514
Carry Forward Securities	Equity	Common Stock, par value $0.001 per share, underlying warrants (exercisable at $9.90)	415(a)(6)	189,405	9.90	$ 1,875,110	0.0001212		S-3	333-231537	5-Jun-19	$ 228.00
Carry Forward Securities	Equity	Common Stock, par value $0.001 per share, underlying warrants (exercisable at $12.375)	415(a)(6)	48,485	12.375	$ 600,002	0.0001212		S-3	333-231537	5-Jun-19	$ 73.00
	Total Offering Amounts					$ 112,475,112		$ 1,392				
	Total Fees Previously Paid							$ 0.00				
	Total Fee Offsets							$ 0.00				
	Net Fees Due							$ 1,392				