

As filed with the Securities and Exchange Commission on December 28, 2022

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

87-0652870
(I.R.S. Employer
Identification Number)

4710 Bellaire Boulevard, Suite 210
Bellaire, Texas 77401
(832) 742-1357

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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

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

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, 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 post-effective amendment filed pursuant to Rule 462(d) 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.

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 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 is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale of these securities is not permitted.

SUBJECT TO COMPLETION, DATED December 28, 2022

PROSPECTUS



800,000 SHARES OF COMMON STOCK

This prospectus relates to the resale from time to time of up to 800,000 shares of our common stock, par value \$0.001 per share, which are issuable upon the exercise of certain warrants held by the selling stockholders named in this prospectus (including shares that may be issued to the holder in lieu of fractional shares). We are not selling any common stock under this prospectus and will not receive any proceeds from the sale of shares listed in this prospectus. We will, however, receive the net proceeds of any warrants exercised for cash in the future.

The selling stockholders may offer and sell the shares from time to time at varying prices and in a number of different ways as each selling stockholder may determine through public or private transactions or through other means described in the section entitled "Plan of Distribution" or a supplement to this prospectus. Each selling stockholder may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "BPTH." The last reported sale price of our common stock on the Nasdaq Capital Market on December 21, 2022 was \$1.32 per share.

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 (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 December , 2022.

TABLE OF CONTENTS

Prospectus	
ABOUT THIS PROSPECTUS	ii
PROSPECTUS SUMMARY	1
THE OFFERING	4
RISK FACTORS	5
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	6
USE OF PROCEEDS	8
SELLING STOCKHOLDERS	9
PLAN OF DISTRIBUTION	12
DESCRIPTION OF CAPITAL STOCK	14
LEGAL MATTERS	16
EXPERTS	16
WHERE YOU CAN FIND MORE INFORMATION	16
INFORMATION INCORPORATED BY REFERENCE	16

ABOUT THIS PROSPECTUS

This prospectus relates to the offering of up to 800,000 shares of our common stock issuable upon the exercise of outstanding warrants (including shares that may be issued to the holder in lieu of fractional shares). Before buying any of the common stock that the selling stockholders 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, 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 125 patients, our DNabilize[®] drug candidates have demonstrated an excellent safety profile. DNabilize[®] is a registered trademark of the Company.

Using DNabilize[®] as a platform for drug development and manufacturing, we currently have four drug candidates in development to treat at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex" i je ber' sen), which targets growth factor receptor-bound protein 2 (Grb2), initially started the efficacy portion of a Phase 2 clinical trial for untreated acute myeloid leukemia ("AML") patients in combination with low-dose cytarabine ("LDAC"). The interim data released on March 6, 2019 showed that 11 (65%) of the 17 evaluable patients had a response, including five (29%) who achieved complete remission ("CR"), inclusive of one CR with incomplete hematologic recovery ("CRi") and one morphologic leukemia-free state, and six (35%) stable disease responses, including two patients who had greater than a 50% reduction in bone marrow blasts. However, DNA hypomethylating agents are now the most frequently used agents in the treatment of elderly AML patients in the U.S. and Europe. As a result, Stage 2 of the Phase 2 trial in AML was amended to remove the combination treatment of prexigebersen and LDAC and replace it with the combination treatment of prexigebersen and decitabine, a DNA hypomethylating agent, for treatment of a second cohort of untreated AML patients. Since decitabine is also used as a treatment for relapsed/refractory AML patients, a cohort of relapsed/refractory AML patients was also added to the study.

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

Our approved amended Stage 2 for this Phase 2 clinical trial currently has three cohorts of patients. The first two cohorts will treat patients with the triple combination of prexigebersen, decitabine and venetoclax. The first cohort will include untreated AML patients, and the second cohort will include relapsed/refractory AML patients. Finally, the third cohort will treat relapsed/refractory AML patients, who are

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

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

Our second drug candidate, Liposomal Bcl-2 (“BP1002”), targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. On November 21, 2019, we announced that the FDA cleared an Investigational New Drug (“IND”) application for BP1002 for an initial Phase 1 clinical trial that will evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients. The Phase 1 clinical trial is being conducted at several leading cancer centers, including The University of Texas MD Anderson Cancer Center (“MD Anderson Cancer Center”) and the Georgia Cancer Center. On November 19, 2020, we announced the enrollment and dosing of the first patient in the Phase 1 clinical trial.

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

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

presented at the 2022 AACR Annual Meeting. We successfully completed several IND enabling studies of BP1003 in 2021 and have one additional IND enabling study to complete. Once the additional study is successfully completed, our goal is to file an IND as soon as the first half of 2023. Based on the filing of the IND, we expect to initiate the first-in-humans Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors, including pancreatic cancer and NSCLC.

In addition, a modified product named BP1001-A, our fourth drug candidate, has shown to enhance chemotherapy efficacy in preclinical solid tumor models. Results of the preclinical study were published in the scientific journal *Oncotarget* in July 2020. BP1001-A incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties. In late 2019, we filed an IND application to initiate a Phase 1/1b clinical trial of BP1001-A in patients with solid tumors, including ovarian, endometrial, pancreatic and breast cancer. Ovarian cancer is one of the most common types of gynecologic malignancies, with approximately 50% of all cases occurring in women older than 63 years. On October 27, 2021, we announced that the FDA cleared the IND application for BP1001-A for the initial Phase 1/1b clinical trial, and on December 7, 2022, we announced the enrollment and dosing of the first patient in the Phase 1/1b 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.

Description of Prior Registered Offering and Private Placement

The shares offered in this prospectus relate to the resale of an aggregate of 800,000 shares of our common stock issuable upon the exercise of the Warrants (as defined below) (including shares that may be issued to the holder in lieu of fractional shares).

On November 9, 2022, we completed the closing of a registered direct offering (the “2022 Registered Direct Offering”) with certain institutional and accredited investors for the sale of an aggregate of 800,000 shares of our common stock for gross proceeds of approximately \$2.0 million. In a concurrent private placement (the “2022 Private Placement”), we issued to the investors in the 2022 Registered Direct Offering warrants to purchase up to 800,000 shares of our common stock, with an exercise price of \$2.85 per share, exercisable from May 9, 2023 until May 9, 2028 (the “Warrants”). We are registering the resale of the shares issuable upon exercise of the Warrants.

THE OFFERING	
Common Stock Offered by the Selling Stockholders	Up to 800,000 shares of our common stock, par value \$0.001 per share, issuable upon exercise of the Warrants (including shares that may be issued to the holder in lieu of fractional shares).
Use of Proceeds	We are not selling any common stock under this prospectus and will not receive any proceeds from the sale of shares listed in this prospectus. We will, however, receive the net proceeds of any Warrants exercised for cash in the future. We currently expect to use such net proceeds, if any, for working capital and general corporate purposes.
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” and “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.

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 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. The risks described in or incorporated by reference in this prospectus also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See “Special Note Regarding Forward-Looking Statements.”

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 “Item 1A. Risk Factors” to Part I of our [Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2021](#) and other factors described elsewhere in this prospectus or in our current and future filings with SEC. As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. You should carefully read this prospectus, together with the information incorporated 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 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 are not selling any common stock under this prospectus and will not receive any proceeds from the sale of shares listed in this prospectus. We will, however, receive the net proceeds of any Warrants exercised for cash in the future. We currently expect to use such net proceeds, if any, for working capital and general corporate purposes. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares. We will not be paying any underwriting discounts or commissions in this offering.

SELLING STOCKHOLDERS

This prospectus covers an aggregate of up to 800,000 shares of our common stock that may be sold or otherwise disposed of by the selling stockholders. Such shares (including shares that may be issued to the holder in lieu of fractional shares) are issuable to the selling stockholders upon the exercise of the Warrants we issued to the selling stockholders in certain private placement transactions. See “Description of Prior Registered Offering and Private Placement” above. When we refer to the “selling stockholders” in this prospectus, we mean the persons and entities listed in the table below, and their respective transferees, donees, pledgees, assignees and successors-in-interest who later come to hold any of the selling stockholders’ interests in shares of the common stock other than through a public sale.

The following table sets forth certain information with respect to each selling stockholder, including (i) the shares of our common stock beneficially owned by the selling stockholder prior to this offering, (ii) the maximum number of shares being offered by the selling stockholder pursuant to this prospectus and (iii) the selling stockholder’s beneficial ownership after completion of this offering, assuming that all of the Warrants are exercised and all of the shares covered hereby (but none of the other shares, if any, held by the selling stockholders) are sold. The registration of the shares of common stock issuable to the selling stockholders upon the exercise of the Warrants does not necessarily mean that the selling stockholders will sell all or any of such shares.

The table is based on information supplied to us by the selling stockholders, with beneficial ownership and percentage ownership determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a selling stockholder and the percentage ownership of that selling stockholder, shares of common stock subject to warrants held by that selling stockholder that are exercisable as of December 21, 2022, or exercisable within 60 days after December 21, 2022, are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. The percentage of beneficial ownership after this offering is based on 7,960,164 shares outstanding on December 21, 2022.

The registration of these shares of common stock does not mean that the selling stockholders will sell or otherwise dispose of all or any of those securities. The selling stockholders may sell or otherwise dispose of all, a portion or none of such shares from time to time. We do not know the number of shares, if any, that will be offered for sale or other disposition by any of the selling stockholders under this prospectus. Furthermore, the selling stockholders may have sold, transferred or disposed of the Warrants or the shares of common stock covered hereby in transactions exempt from the registration requirements of the Securities Act since the date on which we filed this prospectus.

Under the terms of the Warrants, a selling stockholder may not exercise Warrants to the extent that such selling stockholder, together with its affiliates, would beneficially own, after such exercise, more than 4.99% of the shares of common stock then outstanding (subject to the right of the selling stockholder to increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%) and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered. Substantially similar beneficial ownership limitations are found in other warrants to purchase common stock held by the selling stockholders, where applicable. The number of shares in the second column below does not reflect these beneficial ownership limitations. The selling stockholders may sell all, a portion or none of their shares in this offering. See “Plan of Distribution” below.

To our knowledge and except as noted below, none of the selling stockholders has, or within the past three years has had, any position, office or other material relationship with us or any of our predecessors or affiliates.

Selling Stockholders	Number of Shares Beneficially Owned Prior to the Offering	Percent	Maximum Number Offered by Selling Stockholder ⁽⁶⁾	Number of Shares Beneficially Owned After Completion of Offering ⁽⁷⁾	Percent ⁽⁷⁾
Armistice Capital Master Fund Ltd.	180,000 ⁽¹⁾	2.21%	180,000	—	—
CVI Investments, Inc.	333,628 ⁽²⁾	4.11%	160,000	173,628	1.98%
Hudson Bay Master Fund Ltd.	215,142 ⁽³⁾	2.64%	200,000	15,142	*
Intracoastal Capital, LLC	97,890 ⁽⁴⁾	1.22%	60,000	37,890	*
Walleye Opportunities Master Fund Ltd.	386,803 ⁽⁵⁾	4.74%	200,000	186,803	2.13%

* Less than 1%

- (1) The shares of common stock reported herein are held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the “Master Fund”), and may be deemed to be indirectly beneficially owned by (i) Armistice Capital, LLC (“Armistice Capital”), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice Capital and Steven Boyd disclaim beneficial ownership of the securities except to the extent of their respective pecuniary interests therein. The shares of common stock are issuable only upon the exercise of Warrants, which are subject to a 4.99% beneficial ownership limitation prohibiting the Master Fund from exercising any portion of those Warrants if such exercise would result in the Master Fund owning a percentage of our outstanding common stock exceeding the 4.99% ownership limitation after giving effect to the issuance of common stock in connection with the Master Fund’s exercise of any portion of the Warrants.
- (2) Consists of: (1) 22,113 shares of common stock; (2) 151,515 shares of common stock underlying warrants issued on November 25, 2019 with an exercise price of \$9.90 per share; and (3) 160,000 shares of common stock underlying its Warrants. Heights Capital Management, Inc., the authorized agent of CVI Investments, Inc. (“CVI”), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares.
- (3) Consists of: (1) 5,526 shares of common stock; (2) 9,616 shares of common stock underlying warrants issued on September 25, 2018 with an exercise price of \$19.20 per share; and (3) 200,000 shares of common stock underlying its Warrants. The securities are directly held by Hudson Bay Master Fund Ltd., a Cayman Islands exempted company (the “Hudson Bay Fund”). Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities. The address of Hudson Bay Capital Management L.P. is 28 Havemeyer Place, 2nd Floor, Greenwich, CT 06830.
- (4) Consists of: (1) 37,890 shares of common stock underlying warrants issued on November 25, 2019 with an exercise price of \$9.90 per share; and (2) 60,000 shares of common stock underlying its Warrants. The securities are directly held by Intracoastal Capital, LLC, a Delaware limited liability company (“Intracoastal”). Mitchell P. Kopin and Daniel B. Asher, each of whom are managers of Intracoastal, have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. The address of Intracoastal Capital, LLC is 245 Palm Trail, Delray Beach, Florida 33483.
- (5) Consists of: (1) 186,803 shares of common stock; and (2) 200,000 shares of common stock underlying its Warrants. The securities are directly held by Walleye Opportunities Master Fund Ltd, a Cayman Islands exempted company (the “Master Fund”), and may be deemed to be indirectly beneficially owned by: (i) Walleye Capital LLC (“Walleye Capital”), as the investment manager of the Master Fund.

Walleye Capital LLC disclaims beneficial ownership of the securities. The address of the Master Fund is c/o Walleye Opportunities Master Fund Ltd., 2800 Niagara Lane North, Plymouth, Minnesota 55447.

- (6) Represents the maximum number of shares of common stock that may be offered by the selling stockholder based on the assumption that all of the outstanding Warrants held by the selling stockholder will be exercised for cash, irrespective of limitations on exercise.
- (7) Represents the number of shares of common stock that will be beneficially owned by the selling stockholder after completion of this offering based on the assumptions that (i) all of the Warrants held by all selling stockholders will be exercised; (ii) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold and (iii) no other shares of common stock will be acquired or sold by the selling stockholders before completion of this offering. Applicable percentage ownership following the offering is based on 8,760,164 shares of common stock that would be outstanding assuming the exercise of all of the Warrants and all shares registered by this prospectus are sold in the offering.

PLAN OF DISTRIBUTION

The selling stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus from time to time on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling the shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser in amounts to be negotiated.

In connection with a sale of the shares or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus, as supplemented or amended to reflect such transaction.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Because the selling stockholders may be deemed to be “underwriters” within the meaning of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act.

To our knowledge, there are currently no plans, arrangements or understandings between the selling stockholders and any underwriter, broker-dealer or agent regarding the sale of the shares covered by this prospectus by such selling stockholders. If any selling stockholder notifies us that a material arrangement has been entered into with an underwriter, broker-dealer or other agent for the sale of shares through a block trade, special offering or secondary distribution, we may be required to file a prospectus supplement pursuant to applicable SEC rules promulgated under the Securities Act.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common

stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from the sale of the shares by the selling stockholders. We will bear all costs, expenses and fees in connection with the registration of the shares.

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 December 21, 2022, there were 7,960,164 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

Holders of common stock are entitled to one vote for each share held in the election of directors and on all other matters submitted to a vote of stockholders. Cumulative voting of shares of common stock is prohibited. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election.

Subject to the prior rights of the holders of any outstanding preferred stock, holders of common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available therefor. Upon the liquidation, dissolution or winding up of our company, the holders of common stock are entitled to receive ratably the assets of our company remaining after payment of all liabilities and payment to holders of preferred stock if such preferred stock has an involuntary liquidation preference over the common stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable.

As of December 21, 2022, there were approximately 191 holders of record of our common stock.

Preferred Stock

The board of directors is authorized, without any further notice to or action of the stockholders, to issue 10,000,000 shares of preferred stock in one or more series and to determine the relative rights, preferences and privileges of the shares of any such series.

Limitation on Liability and Indemnification of Officers and Directors

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

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

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

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

- authorize our board of directors, without further action by the stockholders, to issue shares of preferred stock in one or more series, and with respect to each series, to fix the number of shares constituting that series and establish the rights and other terms of that series;

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

Business Combinations

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

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

Generally, a business combination includes a merger, consolidation, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an interested stockholder is a person who, together with that person's affiliates and associates, owns, or within the previous three years owned, 15% or more of our voting stock. However, in the case of our company, the sponsors and any of their respective permitted transferees receiving 15% or more of our voting stock, such stockholders will not be deemed to be interested stockholders regardless of the percentage of our voting stock owned by them. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us.

Listing

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

Transfer Agent and Registrar

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

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Winstead PC, Houston, Texas.

EXPERTS

The consolidated financial statements of Bio-Path Holdings, Inc. appearing in Bio-Path Holdings, Inc.'s [Annual Report \(Form 10-K\) for the year ended December 31, 2021](#), have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the securities offered hereby, we refer you to the registration statement and the exhibits filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us. The SEC's Internet site can be found at <http://www.sec.gov>. In addition, we make available on or through our Internet site copies of these reports as soon as reasonably practicable after we electronically file or furnished them to the SEC. Our Internet site can be found at <http://www.biopathholdings.com>. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

INFORMATION INCORPORATED BY REFERENCE

We are incorporating by reference into this prospectus certain information that we file with the SEC, which means that we are disclosing important information to you by referring you to those documents. The information incorporated by reference is deemed to be part of this prospectus, except for information incorporated by reference that is superseded by information contained in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any statements in the prospectus or any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents set forth below that we have previously filed with the SEC:

- [our Annual Report on Form 10-K for the fiscal year ended December 31, 2021](#);
- our Quarterly Reports on Form 10-Q for the quarters ended [March 31, 2022](#), [June 30, 2022](#), and [September 30, 2022](#);
- our Current Reports on Form 8-K filed with the SEC on [February 18, 2022](#), [February 25, 2022](#), [April 6, 2022](#) (other than information furnished under Item 7.01 and exhibits related thereto) and [December 20, 2022](#);
- [our Definitive Proxy Statement on Schedule 14A relating to our 2022 Annual Meeting of Stockholders, filed October 28, 2022](#); and
- [the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on March 5, 2014, including all amendments and reports filed for purposes of updating such description](#).

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

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

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

Bio-Path Holdings, Inc.
Attention: Secretary
4710 Bellaire Boulevard, Suite 210
Bellaire, Texas 77401
(832) 742-1357



800,000 SHARES OF COMMON STOCK

, 2022

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. 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.

	<u>AMOUNT</u>
SEC registration fee	\$ 120
Printing and related expenses	\$ 2,500
Legal fees and expenses	\$20,000
Accounting fees and expenses	\$10,000
Miscellaneous expenses	<u>\$ 1,000</u>
Total	<u><u>\$33,620</u></u>

Item 14. 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 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities issued by the Company since January 1, 2019 that were not registered under the Securities Act. Also included is the consideration received by the Company for such securities and information relating to the section of the Securities Act or rule of the SEC under which exemption from registration was claimed.

- (1) On January 14, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC relating to an underwritten public offering of 429,616 shares of our common stock for gross proceeds of approximately \$1.1 million under our shelf registration statement on Form S-3 (File No. 333-215205), which became effective on January 9, 2017 (the “2019 Underwritten Offering”). Additionally, we issued warrants to purchase up to 25,777 shares of our common stock with an exercise price of \$3.25 per share, exercisable from January 17, 2019 until January 14, 2024 (the “2019 Underwriter Warrants”), in a private placement to H.C. Wainwright & Co., LLC as part of its compensation as the underwriter for the 2019 Underwritten Offering. The 2019 Underwritten Offering and the concurrent private placement closed on January 17, 2019. The 2019 Underwriter Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder.
- (2) On January 18, 2019, we entered into securities purchase agreements with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 648,233 shares of our common stock for gross proceeds of approximately \$1.7 million under our effective shelf registration statement on Form S-3 (File No. 333-215205), which became effective on January 9, 2017 (the “January 2019 Registered Direct Offering”). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 324,117 shares of our common stock (the “January 2019 Private Placement”) with an exercise price of \$2.65 per share, exercisable from January 23, 2019 until July 24, 2024 (the “2019 Series A Warrants”). Additionally, we issued warrants to purchase up to 38,894 shares of our common stock with an exercise price of \$3.3125 per share, exercisable from January 23, 2019 until January 18, 2024 (the “January 2019 Placement Agent Warrants”), in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the January 2019 Registered Direct Offering and the January 2019 Private Placement. The January 2019 Registered Direct Offering and the January 2019 Private Placement closed on January 23, 2019. The 2019 Series A Warrants and the January 2019 Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder. Each investor represented that it was an accredited investor, as defined in Rule 501 of Regulation D promulgated under the Securities Act.
- (3) On March 12, 2019, we entered into securities purchase agreements with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 712,910 shares of our common stock for gross proceeds of approximately \$18.5 million under our effective shelf registration statement on Form S-3 (File No. 333-215205), which became effective on January 9, 2017 (the “March 2019 Registered Direct Offering”). Additionally, we issued warrants to purchase up to 42,775 shares of our common stock with an exercise price of \$32.4375, exercisable from March 14, 2019 until March 12, 2024, in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the March 2019 Registered

Direct Offering. The March 2019 Registered Direct Offering closed on March 14, 2019. The March 2019 Placement Agent Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder.

- (4) On November 9, 2022, we completed the closing of the 2022 Registered Direct Offering with certain institutional and accredited investors for the sale of an aggregate of 800,000 shares of our common stock for gross proceeds of approximately \$2.0 million. On November, 9, 2022, we also completed the concurrent 2022 Private Placement, in which we issued to the investors in the 2022 Registered Direct Offering the Warrants to purchase up to 800,000 shares of our common stock, with an exercise price of \$2.85 per share, exercisable from May 9, 2023 until May 9, 2028. The shares offered in the prospectus forming a part of this Registration Statement include the resale of up to 800,000 shares of our common stock issuable upon exercise of the Warrants. The Warrants were issued in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder. Each investor represented that it was an accredited investor, as defined in Rule 501 of Regulation D promulgated under the Securities Act.

Item 16. Exhibits.

(a) Exhibits

Exhibit Number	Exhibit
2.1	<u>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).</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
3.4	<u>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).</u>
4.1	<u>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).</u>
4.2	<u>Form of Warrant issued to Maxim Group LLC, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K on January 21, 2014).</u>
4.3	<u>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 June 29, 2016).</u>
4.4	<u>Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.5 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2016).</u>
4.5	<u>Form of New Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 22, 2017).</u>
4.6	<u>Form of Warrant Amendment (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 19, 2017).</u>

Exhibit Number	Exhibit
4.7	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 6, 2017).
4.8	Form of Warrant issued to Roth Capital Partners, LLC (incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 10-K filed on April 2, 2018).
4.9	Form of Series A Warrant issued to certain investors (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on September 21, 2018).
4.10	Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2018).
4.11	Form of Underwriter Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
4.12	Form of Series A Warrant issued to certain investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 22, 2019).
4.13	Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.15 to the Company's Annual Report on Form 10-K filed on March 19, 2019).
4.14	Form of Warrant issued to H.C. Wainwright & Co., LLC and certain of its designees (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 13, 2019).
4.15	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).
4.16	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).
4.17	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 9, 2022).
4.18	Description of Bio-Path Holdings, Inc.'s Securities Registered under Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.17 to the Company's Annual Report on Form 10-K filed on March 5, 2020).
5.1*	Opinion of Winstead PC
10.1+	Employment Agreement — Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 19, 2008).
10.2+	Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed on December 10, 2008).
10.3+	First Amendment to First Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013).
10.4	Form of Securities Purchase Agreement by and between the Company, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 21, 2014).
10.5	Form of Waiver, Consent and Amendment to that certain Securities Purchase Agreement by and between Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K on January 21, 2014).
10.6+	First Amendment to Employment Agreement, dated March 26, 2014 — Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 26, 2014).

Exhibit Number	Exhibit
10.7	<u>Lease Agreement dated April 16, 2014 by and between the Company and Pin Oak North Parcel TT, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2014).</u>
10.8	<u>Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 16, 2015).</u>
10.9	<u>Controlled Equity OfferingSM Sales Agreement, dated June 24, 2015, by and between the Company and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on June 25, 2015).</u>
10.10	<u>Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 29, 2016).</u>
10.11	<u>Form of Warrant Exercise Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 22, 2017).</u>
10.12	<u>Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 6, 2017).</u>
10.13	<u>Form of Leak-Out Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 6, 2017).</u>
10.14+	<u>Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.15	<u>Form of Incentive Stock Option Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.16	<u>Form of Non-Qualified Stock Option Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.17	<u>Form of Restricted Share Unit Award Agreement (Time-Vested) under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.18	<u>Form of Restricted Share Unit Award Agreement (Performance-Based) under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.19	<u>Form of Restricted Share Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.20	<u>Form of Stock Appreciation Right Award Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on December 27, 2017).</u>
10.21	<u>Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2018).</u>
10.22	<u>Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2019).</u>
10.23	<u>Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 13, 2019).</u>

Exhibit Number	Exhibit
10.24	<u>First Amendment to Lease Agreement dated April 16, 2014 by and between the Company and Pin Oak North Parcel TT, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 4, 2019).</u>
10.25	<u>Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 22, 2019).</u>
10.26	<u>First Amendment to Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 23, 2019).</u>
10.27	<u>Second Amendment to Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 14, 2020).</u>
10.28	<u>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).</u>
10.29	<u>Form of Securities Purchase Agreement by and between the Company and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 17, 2021).</u>
10.30+	<u>Second Amendment to Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 16, 2022).</u>
10.31	<u>Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 9, 2022).</u>
10.32+	<u>Bio-Path Holdings, Inc. 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
10.33+	<u>Form of Incentive Stock Option Award Agreement under 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
10.34+	<u>Form of Non-Qualified Stock Option Award Agreement under 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
10.35+	<u>Form of Restricted Share Unit Award Agreement (Time-Vested) under 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
10.36+	<u>Form of Restricted Share Unit Award Agreement (Performance-Based) under 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
10.37+	<u>Form of Restricted Share Award Agreement under 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
10.38+	<u>Form of Stock Appreciation Right Award Agreement under 2022 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on December 20, 2022).</u>
21.1	<u>Subsidiaries of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on March 5, 2020).</u>
23.1*	<u>Consent of Ernst & Young LLP.</u>
23.2*	<u>Consent of Winstead PC (included in Exhibit 5.1).</u>
24.1*	<u>Power of attorney (contained on the signature page).</u>

Exhibit Number	Exhibit
107*	Filing Fee Table

* Filed herewith.

+ Management contract or compensatory plan.

(b) Financial statement schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

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 change in volume and price represents no more than a 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 under the Securities Act;

(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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant 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 December 28, 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	December 28, 2022
<hr/> Peter H. Nielsen President, Chief Executive Officer (Principal Executive Officer), Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) and Director	
/s/ Heath W. Cleaver	December 28, 2022
<hr/> Heath W. Cleaver Director	
/s/ Paul D. Aubert	December 28, 2022
<hr/> Paul D. Aubert Director	
/s/ Aline Sherwood	December 28, 2022
<hr/> Aline Sherwood Director	
/s/ Douglas P. Morris	December 28, 2022
<hr/> Douglas P. Morris Director and Secretary	



Austin | Charlotte | Dallas | Fort Worth | Houston | New York | San Antonio | The Woodlands

December 28, 2022

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

Ladies and Gentlemen:

We have acted as legal counsel to Bio-Path Holdings, Inc., a Delaware corporation (the "Company"), in connection with the filing with the Securities and Exchange Commission (the "Commission") of a registration statement on Form S-1 (the "Registration Statement") under the Securities Act of 1933, as amended (the "Securities Act"), including a prospectus (the "Prospectus") which forms a part of the Registration Statement, relating to the resale of 800,000 shares (the "Warrant Shares") of the Company's common stock, par value \$0.001 per share, that may be issued upon the exercise of certain outstanding common stock purchase warrants issued by the Company on November 9, 2022 (the "Warrants"), including shares that may be issued to a Warrant holder in lieu of fractional shares. The Warrant Shares may be offered and sold by the selling stockholders referred to in the Prospectus.

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 Prospectus; (iii) the respective Warrants; (iv) the Certificate of Incorporation of the Company, as currently in effect; and (v) the First Amended and Restated Bylaws of the Company, as currently in effect. 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 opinion 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 (other than persons signing on behalf of the Company); (iii) the authenticity of all documents, certificates and instruments 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 opinion 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. We have also assumed that, at or prior to the time of the issuance and delivery of any Warrant Shares, that there will not have occurred any change in law, change in the Warrants or the Company's Certificate of Incorporation, or further action by the Company's board of directors, in each case affecting the validity of the issuance of the Warrant Shares.

Based on the foregoing and subject to the assumptions, qualifications and limitations set forth herein, as of the date hereof, we are of the opinion that the Warrant Shares have been duly authorized and, upon the valid exercise in accordance with the terms of the respective Warrants 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 the foregoing). 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.

We hereby consent to the reference to our firm under the heading "Legal Matters" in the 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 Commission promulgated thereunder.

Very truly yours,

/s/ Winstead PC

Winstead PC

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-1 No. 333-XXXXX) and related Prospectus of Bio-Path Holdings, Inc. for the registration of 800,000 shares of its common stock underlying warrants 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
December 28, 2022

Calculation of Filing Fee Tables

Form S-1
(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 (1)	Equity	Common Stock, par value \$0.001 per share	457(c)	800,000	\$1.35	\$1,080,000.00	0.00011020	\$120.00				
Fees Previously Paid	—	—	—	—	—	—		—				
Carry Forward Securities												
Carry Forward Securities	—	—	—	—		—			—	—	—	—
	Total Offering Amounts					\$1,080,000.00		\$120.00				
	Total Fees Previously Paid							\$0.00				
	Total Fee Offsets							\$0.00				
	Net Fees Due							\$120.00				

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act, based on the average of the high and low prices of the common stock of the registrant as reported on the Nasdaq Capital Market on December 21, 2022.