

BIO-PATH HOLDINGS INC  
Form 424B5  
March 13, 2019

**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-215205**

**PROSPECTUS SUPPLEMENT**

(To Prospectus dated January 9, 2017)

## **712,910 SHARES OF COMMON STOCK**

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 712,910 shares of our common stock, par value \$0.001 per share, to certain institutional investors at an offering price of \$25.95 per share.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "BPTH." On March 11, 2019, the last reported sales price per share of our common stock on the Nasdaq Capital Market was \$32.44. As of the date of this prospectus supplement, the aggregate market value of our outstanding common stock held by non-affiliates, computed by reference to the price at which our common stock was last sold on March 7, 2019, was \$68,406,618.10, based on 1,794,329 shares of our outstanding common stock as of the date of this prospectus supplement, of which 1,760,335 shares were held by non-affiliates. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million. Following the sale of shares in this offering, we will have sold securities with an aggregate market value of \$22,802,199.54 pursuant to General Instruction I.B.6 of Form S-3 during the 12-month calendar period that ends on and includes the date hereof.

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

	<b>Per Share</b>	<b>Total</b>
Offering price	\$25.95	\$ 18,500,014.50

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Placement agent fees (1)	\$1.81650	\$1,295,001.02
Proceeds, before expenses, to us (2)	\$24.13350	\$17,205,013.49

(1) In addition, we have agreed to pay the placement agent \$85,000 for non-accountable expenses and to issue to the placement agent warrants to purchase shares of our common stock as described under the “Plan of Distribution” on page S-14 of this prospectus supplement.

(2) The amount of the offering proceeds to us presented in this table does not give effect to the sale or exercise, if any, of the warrants being issued to the placement agent.

We have retained H.C. Wainwright & Co., LLC to act as our exclusive placement agent in connection with this offering. The placement agent is not purchasing the securities offered by us in this offering, and is not required to sell any specific number or dollar amount of securities, but will assist us in this offering on a reasonable best efforts basis. We have agreed to pay the placement agent a cash fee equal to 7% of the gross proceeds received from investors who purchase securities in the offering. In addition, we have agreed to pay the placement agent \$85,000 for non-accountable expenses and to issue to the placement agent warrants to purchase shares of our common stock as described under the “Plan of Distribution” on page S-14 of this prospectus supplement.

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

Delivery of the shares of common stock offered hereby is expected to take place on or about March 14, 2019, subject to satisfaction of certain conditions.

**H.C. Wainwright & Co.**

Prospectus supplement dated March 12, 2019

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**Prospectus**

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## **ABOUT THIS PROSPECTUS SUPPLEMENT**

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

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

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

## PROSPECTUS SUPPLEMENT SUMMARY

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

### **Our Company**

We are a clinical and preclinical stage oncology focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNAbilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body’s enzymes when circulating in vivo, incorporated inside of a neutral charged lipid bilayer. 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 proteins in blood diseases and solid tumors. DNAbilize® is a registered trademark of the Company.

Using DNAbilize® as a platform for drug development and manufacturing, we currently have three antisense drug candidates in development to treat at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex’ i je ber’ sen), is in the efficacy portion of a Phase 2 clinical trial for acute myeloid leukemia (“AML”) in combination with low-dose cytarabine (“LDAC”) and in combination with decitabine. On March 6, 2019, we announced intended amendments to this Phase 2 clinical trial to, among other things, add prexigebersen in combination with decitabine for myelodysplastic syndrome (“MDS”) and close prexigebersen in combination with LDAC. In addition, preclinical efficacy studies are underway for triple combination prexigebersen, decitabine and Venclaxta in AML. Prexigebersen is also being studied in the safety portion of a Phase 2a clinical trial for chronic myeloid leukemia (“CML”) in combination with dasatinib. Prexigebersen was shown to enhance chemotherapy efficacy in preclinical solid tumor models, and we intend to file an Investigational New Drug (“IND”) application for prexigebersen in solid tumors in 2019.

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. We are currently preparing an IND application for BP1002 in addition to completing additional IND enabling studies. We intend to initiate a Phase 1 clinical trial of BP1002 in

refractory/relapsed lymphoma and chronic lymphocytic leukemia patients once we receive approval from the U.S. Food and Drug Administration (“FDA”).

Our third drug candidate, Liposomal Stat3 (“BP1003”), targets the Stat3 protein and is currently in preclinical development in a pancreatic patient derived tumor model. Preclinical models have shown BP1003 to successfully penetrate pancreatic tumors and to significantly enhance the efficacy of standard frontline treatments. Our lead indication for BP1003 is pancreatic cancer due to the severity of this disease and the lack of effective, life-extending treatments. We intend to initiate IND enabling studies of BP1003 in 2019.

Our DNAbilize® technology-based products are available for out-licensing or partnering. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means 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, 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. On July 19, 2017, we announced that the United States Patent and Trademark Office issued a notice of allowance for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases.

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

On April 3, 2018, we released the interim data from Stage 1 of the Phase 2 clinical trial for AML in combination with LDAC. The prexigebersen and LDAC combination therapy was well-tolerated and showed early anti-leukemic activity in nearly 50% of evaluable AML patients, including four patients with complete remission (“CR”) and four with stable disease. On August 27, 2018, we announced that we commenced Stage 2 of the Phase 2 clinical trial for AML and added a cohort of patients to be treated with a combination of prexigebersen and decitabine, another AML frontline therapy. On March 6, 2019, we announced updates to the interim analysis from Stage 1 of the Phase 2 clinical trial. We announced that the efficacy profile improved to where 11 (65%) of the 17 evaluable patients had a response, including five (29%) who achieved CR, including one complete remission 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. The efficacy data from the 17 evaluable patients was very favorable compared to the reported CR, CRp (complete remission with incomplete platelet recovery) and CRi rates of 7-13% with LDAC treatment alone. Importantly, through investigation by the principal investigators, it was observed that 68% of patients were secondary AML patients, a difficult class to treat. On March 6, 2019, we also announced intended amendments to this Phase 2 clinical trial to, among other things, add prexigebersen in combination with decitabine for MDS and close prexigebersen in combination with LDAC.

In addition to the Phase 2 trial for AML, a Phase 1b/2a clinical trial, which is the safety portion of the Phase 2 clinical trial, of prexigebersen for the treatment of CML in accelerated and blast phase patients is open for enrollment. The trial is being conducted at MD Anderson as a potential salvage therapy for accelerated and blast phase CML patients. Two cohorts of three evaluable patients each will be enrolled to evaluate two doses (60 mg/ m<sup>2</sup> and 90 mg/ m<sup>2</sup>) of prexigebersen in combination with the front-line treatment dasatinib.

## **Recent Developments**

On January 17, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on January 18, 2019. All common stock share and per share amounts in this prospectus supplement have been adjusted to give effect to the 1-for-20 reverse stock split; however, common stock share and per share amounts in the accompanying prospectus have not been adjusted to give effect to the 1-for-20 reverse stock split.

On January 14, 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the “Underwriter”) relating to an underwritten public offering of 429,616 shares of our common stock (the “2019 Underwritten Offering”) 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 offering price to the public in the 2019 Underwritten Offering was \$2.60 per share, and the Underwriter agreed to purchase the shares in the 2019 Underwritten Offering from the Company pursuant to the underwriting agreement at a price of \$2.418 per share. Additionally, we issued warrants to purchase up to 25,777 shares of our common stock in a private placement to the Underwriter as compensation for its services as underwriter in connection with the 2019 Underwritten Offering. The



2019 Underwritten Offering closed on January 17, 2019. The net proceeds to the Company from the 2019 Underwritten Offering, after deducting the underwriting discounts and commissions and expenses and the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the underwriter warrants, were approximately \$0.9 million.

On January 18, 2019, we entered into a securities purchase agreement 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 "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 "2019 Private Placement"). Additionally, we issued warrants to purchase up to 38,894 shares of our common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the 2019 Registered Direct Offering and the 2019 Private Placement. The 2019 Registered Direct Offering and the 2019 Private Placement closed on January 23, 2019. The net proceeds to us from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately \$1.5 million.

## **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 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.

On February 8, 2018, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-10, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on February 9, 2018. In addition, as described above, on January 17, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on January 18, 2019. All common stock share and per share amounts in this prospectus supplement have been adjusted to give effect to both the 1-for-10 reverse stock split and the 1-for-20 reverse stock split; however, common stock share and per share amounts in the accompanying prospectus have not been adjusted to give effect to such reverse stock splits.

Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357. Our Internet address is [www.biopathholdings.com](http://www.biopathholdings.com). None of the information on our website forms a part of, or incorporated by reference into, this prospectus supplement or the accompanying prospectus.

## The Offering

Common stock offered by us	712,910 shares.
Common stock to be outstanding immediately after this offering (1)	2,507,239 shares (assuming that we sell the maximum number of shares of common stock offered in this offering and excluding shares issuable upon the exercise of the warrants issued to the placement agent).
Offering price per share	\$25.95 per share.
Use of proceeds	We currently expect to use the net proceeds from this offering for working capital and general corporate purposes. See “Use of Proceeds.”
Risk factors	An investment in our company involves a high degree of risk. Please refer to the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before investing our securities.
Nasdaq Capital Market Symbol	“BPTH”

(1) The number of shares of common stock to be outstanding after this offering is based on 1,794,329 shares of our common stock outstanding as of the date of this prospectus supplement (subject to adjustment based on issuances of fractional shares resulting from the 1-for-20 reverse stock split effected as of 5:00 p.m. Eastern Time on January 17, 2019), which excludes, as of such date:

- 37,067 shares of common stock reserved for issuance upon the exercise of outstanding options granted under our equity incentive plans with a weighted average exercise price of \$112.52 per share;
- 40,100 additional shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan;
- 537,906 shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of \$16.87 per share; and
- 42,775 shares of common stock issuable upon exercise of the warrants to be issued to the placement agent in connection with this offering with an exercise price of \$32.4375 per share.

## **RISK FACTORS**

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

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

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

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on an offering price of \$25.95 per share of common stock, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately \$17.08 per share in the net tangible book value of the common stock. See the section titled “Dilution” in this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

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

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

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

We currently intend generally to use the net proceeds from this offering for working capital and general corporate purposes. Our management will have significant flexibility in applying the net proceeds of this offering. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costly to raise funds in the future.

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

As of September 30, 2018, we had an accumulated deficit of \$45.8 million. To date, we have not generated any revenue from the sale of our drug candidates and we do not expect to generate any revenue from sales of our drug candidates for the foreseeable future. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. As of September 30, 2018, we had cash and cash equivalents of \$2.3 million. As previously reported, we closed the 2019 Underwritten Offering on January 17, 2019 and received net proceeds of approximately \$0.9 million from the 2019 Underwritten Offering. Additionally, on January 23, 2019, we closed the 2019 Registered Direct Offering and received net proceeds of approximately \$1.5 million. Even if this offering is successful, we must raise additional funds in order to continue operating our business.

We expect to finance our foreseeable cash requirements through cash on hand, debt financings and public or private equity offerings. Additionally, we may seek collaborations and license arrangements for our drug candidates. If additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate in accordance with our business plan or we may need to discontinue our operations entirely. We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

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

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the rate of progress, results and costs of completion of the ongoing preclinical trials of prexigebersen, BP1002 and BP1003;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;
- the costs to obtain adequate supply of the compounds necessary for our drug candidates;
- the costs of obtaining regulatory approval of our drug candidates;
- the scope, prioritization and number of drug development programs we pursue;
- the costs for preparing, filing, prosecuting, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies and the costs to develop those products and technologies;
- the costs of future commercializing activities, including product sales, marketing, manufacturing and distribution, of any of our drug candidates or other products for which marketing approval has been obtained;
- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us; and
- competing technological and market developments.

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

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

***We face competition from entities that have developed or may develop therapeutic candidates for our target disease indications, including companies developing novel treatments and technology platforms based on modalities and technology that may be similar to ours. If these companies develop technologies, including delivery technologies, or therapeutic candidates more rapidly than we do, or their technologies are more effective, our ability to develop and successfully commercialize therapeutic candidates may be adversely affected.***

While we believe that our DNABilize® technology is the only delivery method of its type, the area of cancer treatment research is rapidly progressing, with many stakeholders, including for-profit and nonprofit institutions, conducting preclinical and clinical studies of various types of therapeutic products for the same or similar indications for use as our drug candidates. We expect that such work by others will continue, which may make it difficult for us to effectively recruit and enroll a satisfactory number of participants in clinical trials.

Our success will partially depend on our ability to develop therapeutics that are safer and more effective than competing therapeutics. Our commercial opportunity and success will be reduced or eliminated if competing therapeutics are safer, more effective, or less expensive than the therapeutics we develop, or if any are granted exclusive marketing approval by the FDA that precludes the marketing of our drug candidates for a period of time. If our lead drug candidates are approved for the indications we are currently pursuing, they will compete with a range of therapeutic treatments that are either in development or currently marketed. For example, the FDA has recently approved a number of drugs indicated for treatment of AML, some of which may have target patient populations similar to that of our drug candidates.

Many of our competitors may have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain FDA approval for any drug candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals (if we are able to obtain any) for these drug candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing therapeutics could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any therapeutics we may develop. Competitive alternatives may make any drugs that we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our drug candidates, if we are able to obtain regulatory approval to commercialize such drug candidates.

***We may be subject, directly or indirectly, to certain U.S. federal and state healthcare laws and regulations, such as anti-kickback, false claims laws, physician payment transparency laws, or similar fraud and abuse laws, which could expose us to potential criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and others will play a primary role in the recommendation, ordering and utilization of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our products and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment transparency laws and regulations. These laws may impact, among other things, our potential sales, marketing and education programs and our relationships with physicians, patients, and other persons or entities in a position to refer, use, or recommend our future products. The laws that may affect our ability to operate could include, but are not limited to:

the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which may be pursued through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

federal criminal statutes under the Health Insurance Portability and Accountability Act of 1996, which prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

the federal transparency requirements under The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, enacted into law in the United States in March 2010 (known collectively as the "Affordable Care Act"), including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

and

State law equivalents of each of the healthcare laws described above, some of which may be broader in scope and apply regardless of the type of payor, such as state anti-kickback statutes and false claims acts, and state pricing, marketing, and transparency statutes that require us to adopt compliance programs, report pricing information, or disclose payments or other transfers of value to physicians or other covered recipients.



Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws once our products are commercialized. In addition, healthcare reform legislation has strengthened these laws and additional laws or requirements may be implemented in the future. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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Efforts to ensure that our business arrangements comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our existing or future business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Any such actions instituted against us could have a significant adverse impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending against such actions, we may nonetheless be subject to substantial costs, reputational harm and adverse effects on our ability to operate our business.

If any of our employees, agents, or the physicians or other providers or entities with whom we expect to do business are found to have violated applicable laws, we may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, or, if we are not subject to such actions, we may suffer reputational harm for conducting business with persons or entities found, or accused of being, in violation of such laws. Any such events could adversely affect our ability to operate our business and our results of operations.

***Inadequate funding for the FDA, the Securities and Exchange Commission (“SEC”) and other government agencies, or a work slowdown or stoppage at those agencies as part of a broader federal government shutdown, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, including December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough employees and stop critical activities. If a prolonged government shutdown or a series of shutdowns occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to gain access to the public markets and obtain necessary capital in order to properly capitalize and continue our operations

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus contain “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements can be identified by words such as “anticipate,” “expect,” “intend,” “plan,” “believe,” “seek,” “estimate,” “project,” “goal,” “strategy,” “future,” “should,” “will” and variations of these words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties, and changes in circumstances, including but not limited to risk factors incorporated by reference under “Item 1A. Risk Factors” to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and other factors described elsewhere in this prospectus supplement, the accompanying prospectus or in our current and future filings with the SEC. As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. You should carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated by reference herein and therein as described under the sections titled “Where You Can Find More Information,” completely and with the understanding that our actual future results may be materially different from what we expect. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Forward-looking statements include, but are not limited to, statements about:

- our lack of significant revenue to date, our history of recurring operating losses and our expectation of future operating losses;
- our need for substantial additional capital and our need to delay, reduce or eliminate our drug development and commercialization efforts if we are unable to raise additional capital;
- substantial doubt regarding our ability to continue as a going concern;
- 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;
- our need to complete extensive clinical trials and the risk that we may not be able to demonstrate the safety and efficacy of our drug candidates;
- risks that that our clinical trials may be delayed or terminated;

- our ability to obtain domestic and 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;

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- 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 relating to public investigations, fines, enforcement actions and other sanctions by regulatory agencies if we do not comply with regulations applicable to public companies; and
- our ability to maintain compliance with the listing standards of the Nasdaq Capital Market.

Any forward-looking statement made by us in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in other reports or documents we file from time to time with the SEC.

## **USE OF PROCEEDS**

We expect to receive net proceeds from this offering of approximately \$17.0 million after deducting the placement agent fees and estimated offering expenses payable by us, excluding the proceeds we may receive from the exercise of the warrants issued to the placement agent.

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

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**DILUTION**

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

Our net tangible book value per share is determined by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. The historical net tangible book value of our common stock as of September 30, 2018 was approximately \$2.3 million, or \$3.52 per share, based on 665,492 shares of common stock outstanding at September 30, 2018. After giving effect to our sales of common stock in the 2019 Underwritten Offering and the 2019 Registered Direct Offering, the pro forma net tangible book value of our common stock as of September 30, 2018 would have been approximately \$4.7 million, or \$2.72 per share, based on 1,743,341 shares of common stock outstanding.

After giving effect to our sales of common stock in the 2019 Underwritten Offering and the 2019 Registered Direct Offering, as well as our sale of shares of common stock to be sold in this offering, and after deducting the placement agent fees and our estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2018 would have been approximately \$21.8 million, or \$8.87 per share of common stock. This represents an immediate increase in net tangible book value of \$6.15 per share to existing stockholders and an immediate dilution of \$17.08 per share to new investors in this offering. The following table illustrates this dilution on a per share basis:

Offering price per share	\$25.95
Pro forma net tangible book value per share as of September 30, 2018, after giving effect to the 2019 Underwritten Offering and the 2019 Registered Direct Offering	\$2.72
Increase in net tangible book value per share attributable to new investors	\$6.15
As adjusted pro forma net tangible book value per share after the offerings	\$8.87
Dilution per share to new investors	\$17.08

The above discussion and table are based on 665,492 shares of our common stock outstanding as of September 30, 2018, after giving effect to our sales of common stock in the 2019 Underwritten Offering and the 2019 Registered Direct Offering, which excludes as of September 30, 2018:



49,817 shares of common stock reserved for issuance upon the exercise of outstanding options granted under our equity incentive plans with a weighted average exercise price of \$154.20 per share;  
40,100 additional shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan;  
183,701 shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of \$52.20 per share; and  
14,623 shares of common stock issuable upon exercise of outstanding pre-funded warrants with an exercise price of \$0.20 per share.

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

## PLAN OF DISTRIBUTION

Pursuant to an engagement letter dated as of March 11, 2019, we have retained H.C. Wainwright & Co., LLC (“Wainwright”) to act as our exclusive placement agent in connection with this offering. Under the terms of the engagement letter, Wainwright is not purchasing the securities offered by us in this offering, and is not required to sell any specific number or dollar amount of securities, but will assist us in this offering on a reasonable best efforts basis. The terms of this offering were subject to market conditions and negotiations between us, Wainwright and prospective investors. Wainwright will have no authority to bind us by virtue of the engagement letter. Further, Wainwright does not guarantee that it will be able to raise new capital in any prospective offering. Wainwright may engage sub-agents or selected dealers to assist with this offering. We may not sell the entire amount of our shares of common stock offered pursuant to this prospectus supplement.

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

Delivery of the shares of common stock offered hereby is expected to take place on or about March 14, 2019, subject to satisfaction of certain conditions.

We have agreed to pay Wainwright a cash fee equal to 7% of the gross proceeds received from investors who purchase securities in the offering. We will also pay Wainwright \$85,000 for non-accountable expenses and \$10,000 for the clearing expenses in connection with this offering. In addition, we have agreed to issue to Wainwright warrants to purchase up to 42,775 shares of common stock, which represents 6% of the aggregate number of shares of common stock sold in this offering. The placement agent warrants will be exercisable for five years from the effective date of this offering and will have an exercise price of \$32.4375 per share, which represents 125% of the offering price per share. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have granted Wainwright a fifteen-month right of first refusal to act as our exclusive underwriter or placement agent for any further capital raising transactions undertaken by us and certain rights for a tail fee during the twelve-month period following expiration or termination of our engagement letter with Wainwright, subject to certain limitations.

We have agreed to indemnify Wainwright and specified other persons against certain liabilities relating to or arising out of Wainwright's activities under the engagement letter and to contribute to payments that Wainwright may be required to make in respect of such liabilities.

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

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

From time to time, Wainwright may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. Wainwright served as our exclusive placement agent in connection with our registered direct offerings we consummated in July 2016, September 2018 and January 2019 and as the underwriter in connection with our underwritten public offering that we consummated on January 17, 2019, and Wainwright received compensation for each such offering. However, except as disclosed in this prospectus supplement, we have no present arrangements with Wainwright for any further services.

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

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## **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 as of December 31, 2017 and 2016 and for the years then ended incorporated by reference in this prospectus supplement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the shares of common stock being offered hereby. This prospectus supplement and the accompanying prospectus, which constitute a part of the registration statement, do not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the securities offered hereby, we refer you to the registration statement and the exhibits filed thereto. Statements contained in this prospectus supplement and the accompanying prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

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

## **INFORMATION INCORPORATED BY REFERENCE**

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

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30, and September 30, 2018;
- our Definitive Proxy Statement on Schedule 14A relating to our 2018 Annual Meeting of Stockholders, filed November 2, 2018;
- our Current Reports on Form 8-K filed with the SEC on February 5, 2018 (other than information furnished under Item 7.01 and exhibits related thereto); February 9, 2018 (other than information furnished under Item 7.01 and exhibits related thereto); February 26, 2018; September 21, 2018 (other than information furnished under Item 7.01 and exhibits related thereto); November 2, 2018 (other than information furnished under Item 7.01 and exhibits related thereto); December 21, 2018; January 14, 2019; January 16, 2019; January 22, 2019 (other than information furnished under Item 7.01 and exhibits related thereto); and February 5, 2019.
- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on March 5, 2014, as updated by our Current Report on Form 8-K filed with the SEC on January 6, 2015.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus supplement or 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 date of this prospectus supplement until 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 supplement and accompanying prospectus are delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus but not delivered with the prospectus supplement and accompanying prospectus, including exhibits which are specifically incorporated by reference into such documents. You may request a copy of these filings at no cost, by writing to or telephoning us at the following address:

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

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**PROSPECTUS**

**\$125,000,000**

**COMMON STOCK**

**PREFERRED STOCK**

**WARRANTS**

**UNITS**

We may from time to time offer and sell up to \$125,000,000 of common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination of the foregoing, either individually or in units, at prices and on terms described in one or more supplements to this prospectus. We may also offer securities as may be issuable upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including any applicable anti-dilution provisions.

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

Our common stock is currently listed on the NASDAQ Capital Market under the symbol "BPTH." On December 16, 2016, the last reported sales price per share of our common stock on the NASDAQ Capital Market was \$1.20.



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

**Investing in our securities involves a high degree of risk. Before making an investment decision, you should review carefully and consider all of the information set forth in this prospectus, the applicable prospectus supplement and the documents incorporated by reference in this prospectus and applicable prospectus supplement. See “Risk Factors” on page 6 of this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus.**

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

The date of this prospectus is January 9, 2017

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## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration statement process, we may from time to time sell common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination of the foregoing, either individually or in units, in one or more offerings up to an offering amount of \$125,000,000. This prospectus provides you with a general description of the securities we may offer and the general manner in which these securities will be offered.

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

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

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

You should rely only on the information we have provided or incorporated by reference in this prospectus and the applicable prospectus supplement. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or the applicable prospectus supplement. You must not rely on any unauthorized information or representation. This prospectus or any applicable supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus or any applicable supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should assume that the information in this prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section titled “Where You Can Find More Information.”

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

## PROSPECTUS SUMMARY

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

### Our Company

We are a clinical and preclinical stage oncology focused antisense 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 neutral charged lipid bilayer. 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 proteins in blood diseases and solid organs.

Using DNAbilize™ as a platform for drug development and manufacturing, we currently have two antisense drug candidates in development to treat a total of five different disease indications. Our lead drug candidate, Liposomal Grb2 (“BP1001”), targets the protein Grb2 and has entered the efficacy portion of a Phase II clinical trial for acute myeloid leukemia (AML) and is preparing to enter the safety segment of a Phase II clinical trial for blast phase and accelerated phase chronic myelogenous leukemia (CML). BP1001 is also in preclinical studies for solid tumors, including triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC).

Our second drug candidate, Liposomal Bcl2 (“BP1002”), targets the protein Bcl2, which is responsible for driving cell proliferation in up to 60% of all cancers. BP1002 is in preparation for an Investigational New Drug (IND) application.

We currently maintain an exclusive license agreement (the “License Agreement”) with The University of Texas, MD Anderson Cancer Center (“MD Anderson”), under which we license from MD Anderson the delivery technology platform and BP1001 and BP1002. We are developing antisense drug candidates to treat cancer and autoimmune

disorders where targeting a single protein may be advantageous and result in reduced 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 manufacture of neutral charged DNA-liposome complexes.

*BP1001*

We have completed our Phase I clinical trials for BP1001 for indications for AML, CML, MDS and Acute Lymphoblastic Leukemia (ALL). On October 9, 2015, we announced the completion of Cohort 7, the first dosing cohort of the Phase Ib clinical trial, consisting of a 60 mg/m<sup>2</sup> dose of BP1001 in combination with LDAC. On March 3, 2016, we announced the completion of Cohort 8, the second dosing cohort of the Phase Ib clinical trial, consisting of a 90 mg/m<sup>2</sup> dose of BP1001 in combination with LDAC. On June 6, 2016, we announced data from the safety segment of the Phase II combination therapy of BP1001 and LDAC showed no dose limiting toxicities. Of the six evaluable patients, four patients completed more than two cycles of treatment, three patients achieved complete remission and two patients achieved partial remission. Pharmacokinetics of BP1001 demonstrated a half-life at 60 mg/m<sup>2</sup> of 30 hours, significantly better than the 90 mg/m<sup>2</sup> dose. The final analysis of these data, along with the demonstrated reductions in bone marrow blasts, suggested that 60 mg/m<sup>2</sup> was the appropriate dose for use in the Phase II trial. Administratively, this required us to reformat documents for the Phase II trial with the 60 mg/m<sup>2</sup> dose and resubmit for approvals with the FDA and site Institutional Review Boards, requiring additional time prior to starting the Phase II trial.

On November 2, 2016, we announced that the first patient in the efficacy portion of the Phase II trial was dosed. The full trial design includes approximately 54 evaluable patients with an interim analysis to be performed after 19 patients are treated with the combination. In the event the interim results exceed the primary endpoint in the number of patients that meet or exceed statistically determined thresholds, we may seek to convert the trial into a registration trial for accelerated approval. The multi-site trial will be conducted at leading cancer centers, among them are Weill Medical College of Cornell University, Baylor Scott & White Health, The University of Kansas and MD Anderson.

We have also initiated preclinical testing of BP1001 for the treatment of TNBC and IBC. Our plan is to develop BP1001 as a targeted therapy against TNBC and IBC. Our treatment goals are two-pronged: the first is to develop BP1001 as a tumor reduction agent in combination with other approved drugs in preoperative settings for TNBC and IBC patients, and the second is to develop BP1001 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients. Once the preclinical studies are completed, we believe that the observations that we learned from the original Phase I trial will help us increase the speed of progress for such Phase I trial in TNBC and IBC, as the toxicity profile of BP1001 is currently well-established.

#### *BP1002*

BP1002, also known by its scientific name as Liposomal Bcl2, is our second liposome delivered antisense drug candidate. BP1002 is intended to target the lymphoma and certain solid tumor markets. Clinical targets for BP1002 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. We believe that BP1002 has the potential to treat 40 to 60% of solid tumors.

#### *DNAbilize™*

DNAbilize™ technology is available for out-licensing. We intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. A significant amount of capital is expected to be allocated to in-license promising protein targets that can be developed as new liposomal antisense drug candidates. As we expand, we will look at indications where a systemic delivery is needed and antisense can be used to slow, reverse, or cure a disease, either alone or in combination with another drug.

We are interested in pursuing a wide-ranging, proactive licensing program to include co-development of specific liposomal antisense drug candidates, sub-licensing our delivery template for outside development of liposomal antisense drug candidates or out-licensing a partially-developed drug candidate for final development and marketing.

## Corporate Information

We were originally incorporated in May 2000 as a Utah corporation under the name Ogden Golf Co. Corporation, but terminated our retail golf store operations in December 2006. In February 2008, we completed a reverse merger with Bio-Path Subsidiary. The name of Ogden Golf Co. Corporation was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol "BPTH." Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law.

Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357. Our Internet address is [www.biopathholdings.com](http://www.biopathholdings.com). None of the information on our website forms a part of, or incorporated by reference into, this prospectus or any applicable prospectus supplement.



## THE OFFERING

We may offer common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination of the foregoing, either individually or in units, in one or more offerings, with an aggregate initial offering price not to exceed \$125,000,000. This prospectus describes the general terms that may apply to the securities to be offered and the specific terms of any particular securities that we offer will be described in a separate supplement to this prospectus, including, to the extent applicable:

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

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

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

## **RISK FACTORS**

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

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

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference into this prospectus contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Exchange Act. Forward-looking statements can be identified by words such as “anticipate,” “expect,” “intend,” “plan,” “believe,” “seek,” “estimate,” “project,” “goal,” “strategy,” “future,” “likely,” “may,” “should,” “will” and variations of these words, as well as similar references to future periods, although not all forward-looking statements contain these identifying words.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties, and changes in circumstances, including but not limited to risk factors contained in or incorporated by reference under the section titled, “Risk Factors.” As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. You should carefully read this prospectus and any applicable supplement to this prospectus, together with the information incorporated herein by reference as described under the section titled “Where You Can Find More Information,” completely and with the understanding that our actual future results may be materially different from what we expect. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition.

Any forward-looking statement made by us in this prospectus, any applicable supplement to this prospectus and the documents incorporated by reference into this prospectus is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in other reports or documents we file from time to time with the SEC.

## **USE OF PROCEEDS**

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

**RATIO OF EARNINGS TO FIXED CHARGES**

The following table sets forth our ratio of earnings to combined fixed charges and preference securities dividends for each of the periods indicated. The following table is qualified by the more detailed information appearing in the computation table set forth in Exhibit 12.1 to the registration statement of which this prospectus is part and the historical financial statements, including the notes to those financial statements, incorporated by reference in this prospectus.

	Year End December 31,					<b>Nine Months Ended</b>
	2011	2012	2013	2014	2015	<b><u>September 30,</u></b>
						2016
Ratio of earnings to combined fixed charges and preference dividends (1)	—	—	—	—	—	—

(1) Earnings were insufficient to cover combined fixed charges and preference dividends by \$2.4 million in 2011, \$2.6 million in 2012, \$3.3 million in 2013, \$4.5 million in 2014, \$5.5 million in 2015 and \$5.4 million during the nine months ended September 30, 2016.

## **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 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 16, 2016, there were 95,645,224 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

### **Common Stock**

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

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

### **Preferred Stock**

Our preferred stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by our board of directors. Our board of directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of our preferred stock, including without limitation authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. The board of directors is further authorized to increase (but not above the total

number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in our certificate of incorporation or the resolution of our board of directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series. As of the date of this prospectus, no such shares had been designated.

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

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

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



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

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

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

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

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

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

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

### **Limitation on Liability and Indemnification of Officers and Directors**

Our certificate of incorporation and bylaws provide for indemnification of our officers and directors to the fullest extent permitted by Delaware law. Our certificate of incorporation and 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 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 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 bylaws may be amended by our board of directors without stockholder approval;

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 15<sup>th</sup> Avenue, Brooklyn, New York 11219. Its phone number is (800) 937-5449.

### **DESCRIPTION OF WARRANTS**

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

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

## General

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

- the title of the warrants;
- the aggregate number of the warrants offered;
- the price or prices at which the warrants will be issued;

the securities, which may include shares of any class or series of common stock or preferred stock, for which the warrants are exercisable;

in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

- the terms of any rights to redeem or call the warrants;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;

- the terms of any rights to force the exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and the date on which the right will expire;
- if applicable, the minimum or maximum number of warrants that may be exercised at any one time;
- the manner in which the warrant agreements and warrants may be modified;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

- information relating to book-entry procedures, if any;
- the listing of the warrants on a securities exchange or automated quotation system, if any;
- whether the warrants may be sold separately or with other securities as parts of units;

if applicable, a discussion of material United States federal income tax considerations of holding or exercising the warrants; and

any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

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

### **Exercise of Warrants**

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

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

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

### **Enforceability of Rights by Holders of Warrants**

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

## **Warrant Adjustments**

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

## **Warrant Agreement Will Not Be Qualified Under Trust Indenture Act**

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

## **Currently Outstanding Warrants**

As of December 20, 2016, we had issued and outstanding warrants to purchase 5,951,176 shares of our common stock with a weighted exercise price of \$3.43 per share.

## **DESCRIPTION OF UNITS**

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



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

## **General**

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

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

• the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

- any provisions of the governing unit agreement that differ from those described below; and

• any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

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

## **Issuance in Series**

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

### **Enforceability of Rights by Holders of Units**

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

## **LEGAL OWNERSHIP OF SECURITIES**

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

### **Book-Entry Holders**

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

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

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

### **Street Name Holders**

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

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

### **Legal Holders**

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

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

### **Special Considerations for Indirect Holders**

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

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consents, if ever required;

whether and how you can instruct it to send you securities registered in your own name so you can be a registered holder, if that is permitted in the future;

how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and

- if the securities are in book-entry form, how the depository's rules and procedures will affect these matters.

### **Global Securities**

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

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

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

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

### **Special Considerations for Global Securities**

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

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

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;

- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;

- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;

- an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;

the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depositary in any way;

the depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and

financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities

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

### **Special Situations When a Global Security Will Be Terminated**

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

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

• if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;

- if we notify any applicable trustee that we wish to terminate that global security; or

• if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

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



## PLAN OF DISTRIBUTION

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

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

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

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

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

- at prices related to prevailing market prices; or
  
- at negotiated prices.

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

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

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

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

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

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

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

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

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

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

compensation.

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## **LEGAL MATTERS**

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

## **EXPERTS**

Our annual consolidated financial statements incorporated in this prospectus by reference to our Annual Report on Form 10-K for the year ended December 31, 2015, have been audited by Mantyla McReynolds, LLC, an independent registered public accounting firm, to the extent indicated in their report thereon. Such consolidated financial statements are incorporated by reference into this prospectus in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any documents that we have filed with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the operation of the Public Reference Room. The SEC also 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>.

## **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, 2015;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30 and September 30, 2016;
- our Current Reports on Form 8-K filed with the SEC on June 30, August 1 and December 16, 2016; and

the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on March 5, 2014, as updated by our Current Report on Form 8-K filed with the SEC on January 6, 2015.

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

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

We will provide to each person, including any beneficial owner, to whom a prospectus 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

**712,910 SHARES OF COMMON STOCK**

**H.C. Wainwright & Co.**

March 12, 2019