Risk Factors Comparison 2025-03-27 to 2024-03-07 Form: 10-K

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Risk Factor Summary We are providing the following summary of the risk factors disclosed in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage our stockholders to carefully review the risk factors disclosed in this Form 10- K in their entirety for additional information regarding the material factors that make an investment in the Company speculative or risky. ● We are a clinical stage biotechnology company with no significant revenue. We have incurred significant operating losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve profitability. ● We will continue to require substantial additional capital for the foreseeable future. If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our drug development programs and commercialization efforts. ● The pharmaceutical and biotechnology industry is highly competitive. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete. ● Future collaboration arrangements to leverage our capabilities may not be successful. ● If we are unable to attract and retain key management, scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives. ● Our employees, agents, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with applicable regulatory standards and requirements. ● We expect to expand our operations, including clinical trials, in the future and may face challenges in managing our growth, which may result in disruptions to our operations. ● If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction. ● Our business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim could adversely affect our business. ● We are increasingly dependent on information technology systems to operate our business and a cyber- attack or other breach of our systems, or those of third parties on whom we may rely, could subject us to liability or interrupt the operation of our business. ● Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. ● Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult to change management. ● 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. ● 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. ● Inadequate funding for the FDA, the 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. ● Our business and operations have been affected by and could be materially and adversely affected in the future by the effects of health epidemics and pandemics, including the evolving and ongoing effects of the COVID- 19 pandemic. ● Unstable market and economic conditions may have serious adverse effects on our ability to raise funds, which may cause delays, restructuring or cessation of our operations. ● We must complete extensive clinical trials to demonstrate the safety and efficacy of our drug candidates. If we are unable to demonstrate the safety and efficacy of our drug candidates, we will not be successful. ● Delays in the commencement of clinical trials of our drug candidates could result in increased costs to us and delay our ability to generate revenues. ● Delays in the completion of, or the termination of, clinical trials of our drug candidates could result in increased costs to us and could delay or prevent us from generating revenues. ● If we are unable to obtain U. S. and / or foreign regulatory approval, we will be unable to commercialize our drug candidates. ● In addition to regulations in the U. S., we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved. ● Changes in existing laws and regulations affecting the healthcare industry could increase our costs and otherwise adversely affect our business. ● We rely on third parties to conduct clinical trials for our drug candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our drug candidates. ● We may not be able to obtain or maintain orphan drug exclusivity for our product candidates. ● We rely on third parties for manufacturing of our clinical drug supplies; our dependence on these manufacturers may impair the development of our drug candidates. **23** ● There are underlying risks associated with the manufacture of our drug candidates, which have never been manufactured in large scale. Furthermore, we anticipate continued reliance on third- party manufacturers if we are successful in obtaining marketing approval from the FDA or other regulatory agencies for any of our drug candidates. ● Identification of previously unknown problems with respect to a drug candidate, manufacturer or facility may result in restrictions on the drug candidate, manufacturer or facility. ● We may experience delays in the development of our drug candidates if the third- party manufacturers of our drug candidates cannot meet FDA requirements relating to current Good Manufacturing Practices. ~~26~~ ● If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue. ● If our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if

any. ● If third- party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase. ● If our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business. ● If any third- party owners of intellectual property we may license in the future do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed. ● If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. ● Litigation regarding patents, intellectual property and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate. ● Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property. ● Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights. Additionally, sales of a substantial number of shares of our common stock or other securities in the public market could cause our stock price to fall. ● We may issue additional shares of our common stock in accordance with our equity incentive plans or upon exercise or conversion of outstanding securities that are exercisable for or convertible into shares of our common stock, which may cause dilution to existing stockholders. ● The trading price of our common stock has been volatile and is likely to be volatile in the future. ● Our common stock is thinly traded and in the future may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares. ● Our certificate of incorporation grants our Board of Directors the power to designate and issue additional shares of common and / or preferred stock. ● We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us. **24** ● Our management is required to devote substantial time and incur additional expense to comply with public company regulations. ● Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act of 2002 could have a material adverse effect on the price of our common stock. ~~● Our common stock may be delisted from The Nasdaq Capital Market which could negatively impact the price of our common stock and our ability to access the capital markets. 27Risks~~ -- **Risks** Related to Our BusinessWe are a clinical stage biotechnology company with no significant revenue. We have incurred significant operating losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve profitability. We have incurred significant operating losses since our inception. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~107~~ **117** . ~~6~~ **5** 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. To achieve profitability, we must successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability. We will continue to require substantial additional capital for the foreseeable future. If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our drug development programs and commercialization efforts. We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, prexigebersen, BP1002, BP1003 and BP1001- A. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As of December 31, ~~2023~~ **2024** , we had $ 1. ~~1~~ **2** million in cash on hand, compared to $ ~~10~~ **1** . ~~4~~ **1** million as of December 31, ~~2022~~ **2023** . We have determined that the Company' s available cash at December 31, ~~2023~~ **2024** will not be sufficient to fund current liabilities and capital expenditure requirements. 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 ongoing preclinical testing of our drug candidates; ● the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical tests 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; **25** ● 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. ~~28Any~~ -- **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. If our operating plans change, we may require additional capital sooner than planned. Such additional financing may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan. The report of our

independent registered public accounting firm contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern. The report of our independent registered public accounting firm relating to our December 31, ~~2023~~ **2024** consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern. As discussed in Note 2 to the consolidated financial statements included herein, we have suffered recurring losses from operations and have a projected cash deficiency that raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. We have determined that the Company' s available cash at December 31, ~~2023~~ **2024** will not be sufficient to fund current liabilities and capital expenditure requirements. We may 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. We may seek to access the public or private equity markets whenever conditions are favorable. We currently have no lines of credit or other arranged access to debt financing. If we are unable to obtain funding due to unfavorable terms or market conditions, management has determined that it can reduce spending on its day- to- day operations, sell laboratory assets and temporarily delay planned activities if needed. However, our ability to continue as a going concern is dependent upon obtaining funding through one or more sources described above to meet our planned obligations and pay our liabilities. The pharmaceutical and biotechnology industry is highly competitive. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete. We are engaged in segments of the pharmaceutical and biotechnology industry that are highly competitive and characterized by rapid and significant technological change. Many large pharmaceutical and biotechnology companies, academic and research institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target AML, CML, ALL, MDS, lymphoma, ovarian, breast cancer, solid tumors and other cancers generally. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less ~~costly~~ **26costly** than our drug candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our drug candidates. Many of our competitors have: ● significantly greater capital, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates; ~~29~~ ● more experience in drug discovery, development and commercialization, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products; ● drug candidates that have been approved or are in late- stage clinical development; and / or ● collaboration arrangements in our target markets with leading companies and research institutions. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patent registration for clinical trials, and acquiring technologies complementary to, or necessary for, our drug candidates and programs. Competitive products and technological developments may render our drug candidates noncompetitive or obsolete before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and / or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful. Future collaboration arrangements to leverage our capabilities may not be successful. As part of our business strategy, we may enter into collaborative arrangements for the development and commercialization of our drug candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. If we do enter into collaborative arrangements, the success of these collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Furthermore, we may face risks and uncertainties in connection with collaborative arrangements, including: ● inability to integrate the resources or capabilities of collaborators; ● collaborators may prove difficult to work with or less skilled than we originally expected; ● disputes may arise with respect to the ownership of rights to technology developed with collaborators; ● disagreements with collaborators could delay or terminate the research, development or commercialization of products or result in litigation or arbitration; **27** ● difficulty enforcing our arrangements if one of our collaborators fails to perform; ● termination of our collaboration arrangements by collaborators, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities; ● collaborators may have considerable discretion in electing whether to pursue the development of any additional drug candidates and may pursue technologies or products either on their own or in collaboration with our competitors that are similar to or competitive with our technologies; ~~and30~~ -- **and** ● collaborators may change the focus of their development and commercialization efforts. If we are unsuccessful in our collaborative efforts, our ability to develop and market drug candidates could be severely limited. If we are unable to attract and retain key management, scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives. Our success depends on the availability and contributions of members of our senior management team, scientific team and other key personnel. The loss of services of any of

these individuals could delay, reduce or prevent our drug development and other business objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform drug development work will be critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other public and private research institutions. We may be unable to attract and retain these individuals, and our failure to do so could materially adversely affect our business and financial condition. Our employees, agents, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with applicable regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, advisors and commercial partners. Misconduct by these persons could include intentional failures to comply with the regulations of the FDA and non- U. S. regulators, comply with healthcare fraud and abuse laws and regulations in the U. S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our business, financial condition and reputation. We currently have codes of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our codes of business conduct and ethics and the other precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could materially adversely affect our business and financial condition. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations. We expect to expand our operations, including clinical trials, in the future and may face challenges in managing our growth, which may result in disruptions to our operations. We expect to expand our operations, including clinical trials for our drug candidates, over time. To successfully manage future growth, we may need to implement and improve our managerial, operational and financial resources, and may need to expand our facilities and recruit and train additional qualified personnel. Our expected growth may also require significant financial resources, which may not be available when needed or on terms favorable to us. Our senior management may be required to devote substantial attention to managing growth activities and may be unable to effectively manage the expansion of our operations due to our limited resources, which may result in disruptions to our business operations and could harm our business and financial condition. ~~If~~ **28If** we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction. If appropriate opportunities become available, we may license or acquire technologies, resources, drugs or drug candidates. We may never realize the anticipated benefits of such a transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, the creation of contingent liabilities, material impairment expenses related to goodwill and impairment or amortization expenses related to other intangible assets, which could harm our business and financial condition. ~~31Our~~ -- **Our** business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim could adversely affect our business. Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs. We currently have product liability insurance, but we may not be able to maintain such insurance on acceptable terms. However, even if we maintain or obtain other product liability insurance, our insurance may not provide adequate coverage against potential liabilities. As a result, we may be unable to obtain or maintain insurance coverage at a reasonable cost to protect against losses that could harm our business and financial condition. If any claims are brought against us, and we are not successful in defending ourselves, those claims could result in damage awards against us, which could materially adversely affect our business and financial condition. Whether or not we are successful in defending against such claims, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims. We are increasingly dependent on information technology systems to operate our business and a cyber- attack or other breach of our systems, or those of third parties on whom we may rely, could subject us to liability or interrupt the operation of our business. We are increasingly dependent on information technology systems to operate our business. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems by employees, others with authorized access to our systems or unauthorized persons could negatively impact operations. In the ordinary course of business, we collect, store and transmit confidential information and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, we outsource certain elements of our information technology systems to third parties. As a result of this outsourcing, our third party vendors may or could have access to our confidential information making such systems vulnerable. Data breaches of our information technology systems, or those of our third party vendors, may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. For example, the loss of clinical trial data from completed or ongoing clinical trials or preclinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we believe that we have taken appropriate security measures to protect our data and information technology systems, and have been informed by our third party vendors that they have as well, there can be no assurance that

our efforts will prevent breakdowns or breaches in our systems, or those of our third party vendors, that could materially adversely affect our business and financial condition. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under Section 382 of the Internal Revenue Code of 1986, as amended (the " Code "), if a corporation experiences an " ownership change, " generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to utilize its pre- change net operating loss carryforwards and other pre- change tax attributes (such as research tax credits) to offset its post- change taxable income or taxes may be limited. Our prior and potential future equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change under Section 382 of the Code. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities. On December 22, 2017, the U. S. government enacted legislation referred to as the Tax Cuts and Jobs Act (the " Tax Act "). Under the Tax Act, net operating losses generated prior to 2018 will continue to be governed by the net operating loss tax rules as they ~~existed~~ **29existed** prior to the adoption of the new Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Accordingly, our net operating losses could expire unused and be unavailable to offset future income tax liabilities, if any. Under the Tax Act, net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such net operating losses is limited to 80 % of current year taxable income. We continue to examine the impact that this provision of the Tax Act, among other provisions, may have on our business. ~~32Provisions~~ -- **Provisions** of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult to change management. Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders might otherwise consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include: ● limitations on our stockholders' ability to call special meetings of stockholders; ● an advance notice requirement for stockholder proposals and nominations for members of our Board; ● the authority of our Board to determine the number of director seats on our Board; ● the authority of our Board to fill vacancies occurring on the Board; ● the authority of our Board to issue preferred stock with such terms as our Board may determine. In addition, because we are governed by Delaware law, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. 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~~ **30administered** , 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. ~~33We~~ **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 U. S., 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 (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~~ **31implemented** 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 ~~34Act~~ -- **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. 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 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, **in recent** ~~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, which could have a material adverse effect on our business and financial condition. Our business and operations have been affected by and could be materially and adversely affected in the future by the effects of health epidemics and pandemics, including the evolving and ongoing effects of the COVID- 19 pandemic. Our business and operations could be adversely affected by health epidemics and pandemics, including the ongoing COVID- 19 pandemic, which has presented a substantial public health and economic challenge around the world and has affected, and continues to affect, our employees, clinical trial participants, communities, and business operations, as well as the U. S. and global economy and financial markets. To date, COVID 19' s impact on our operations has been limited to the inability to travel to clinical trial sites, clinical trial sites not allowing nonessential personnel on site for the purpose of monitoring activity, delays in the manufacture of our drug requirements by contracted third- party manufacturers and limitations on patient recruiting and enrollment. There can be no guarantee we will not experience other impacts, such as being forced to further delay or pause enrollment, experiencing potential interruptions to our supply chain, facing difficulties or additional costs in enrolling patients in future clinical trials or being able to achieve full enrollment of our studies within the timeframes we anticipate, or at all. ~~35The~~ **32The** negative impacts caused by the COVID- 19 pandemic have been and may continue to be extensive in many aspects of society and could continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. The full extent to which the COVID- 19 pandemic could ultimately impact our business, preclinical studies, clinical trials and financial results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including the emergence of new variants and subvariants of the virus that causes COVID- 19. Other public health crises, including any future outbreaks of contagious diseases, could have additional material adverse effects on our business. The extent to which any future public health crises may impact our business, results of operations, and financial condition depends on many factors which are highly uncertain and are difficult to predict. These factors include, but are not limited to, the duration and spread of any outbreak, its severity, the actions to contain or address the impact of the outbreak, the timing, distribution, and efficacy of vaccines and other treatments, United States and foreign government actions to respond to possible reductions in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume. Unstable market and economic conditions may have serious adverse effects on our ability to raise funds, which may cause delays, restructuring or cessation of our operations. From time to time, global and domestic credit and financial markets have experienced extreme disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make a debt or equity financing more difficult to complete, costlier, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms will have a material adverse effect on our business strategy and financial condition, and could require us to liquidate and dissolve the Company. Risks Related to the Development of Our Drug CandidatesWe must complete extensive clinical trials to demonstrate the safety and efficacy of our drug candidates. If we are unable to demonstrate the safety and efficacy of our drug candidates, we will not ~~be successful~~ **obtain the regulatory approval necessary to market our drug candidates, which would have an adverse effect on our business** . To date, none of our drug candidates have been approved for sale in the U. S. or any foreign country. **Before a new drug product can be marketed, it must obtain clearance from the FDA by submitting an investigational new drug application (" IND "), then by successfully completing human testing under three phases of clinical trials, and finally by submitting a new drug application (" NDA "). Before an entity can begin clinical trials for a product candidate in the U. S., they must complete extensive nonclinical and preclinical studies that support their planned and future INDs. We cannot be certain of the timely completion or outcome of ongoing and future nonclinical and preclinical studies and cannot predict if the FDA will allow our future proposed clinical programs to proceed or if the outcome of their nonclinical and preclinical studies will ultimately support further development of our programs. We also cannot be sure that we will be able to submit INDs or similar applications with respect to our future product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. With respect to INDs we have already obtained or are able to obtain in the future, we cannot be sure that our clinical trials will be successful to the satisfaction of the FDA. For purposes of NDA approval by the FDA, human clinical trials are typically conducted in the following phases (which may overlap): ● Phase 1: The investigational product is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. These trials may also provide early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product' s pharmacokinetics and pharmacologic effects may be obtained to permit the design of well- controlled and scientifically valid Phase 2 clinical trials. ● Phase 2: These clinical trials are conducted in a limited number of human subjects in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the investigational product for specific 33targeted diseases and to determine dosage tolerance and dosage levels. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. ● Phase 3: Phase 3 clinical trials are undertaken after Phase 2 clinical trials demonstrate that a dosage range of the investigational product appears effective and has a tolerable safety profile. The Phase 2 clinical trials must also provide sufficient information for the design of Phase 3 clinical trials. Phase 3 clinical trials are conducted to provide statistically significant evidence of clinical efficacy and to further test for safety risks in an expanded human subject population at multiple clinical trial sites. These clinical trials are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit- risk profile of the investigational product and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well- controlled Phase 3 clinical trials to demonstrate the efficacy of an investigational drug or biologic. All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes. Progress reports**

detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. These government regulations may delay or prevent approval of product candidates for a considerable period of time and impose costly procedures upon our business operations. The FDA may require, or companies may pursue, additional clinical trials, referred to as Phase 4 clinical trials, after a product is approved. Such trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has authority to require sponsors to conduct post- marketing trials to specifically address safety issues identified by the agency. While antisense therapeutics have been in development for over 20 years, only a limited number of antisense drugs have been successfully developed to date. Further, the development of liposomal antisense therapeutics, which comprise our drug therapeutics technology, has faced many challenges and generally remains unproven in the treatment of cancers. The success of our business depends primarily on our ability to develop and commercialize our drug candidates successfully. ~~Our~~ **In order to obtain FDA approval to market a new drug in the U. S., our** drug candidates must satisfy rigorous standards of safety and efficacy **to the satisfaction of the FDA** before they ~~can~~ **may** be approved for sale. ~~To~~ **In an effort to** satisfy these standards, we must engage in expensive and lengthy testing of our drug candidates. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to move on to further efficacy segments of our ongoing clinical trials or commence and complete any other clinical trials for any of our drug candidates. Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in early- stage development. Accordingly, the results from the preclinical tests or clinical trials for our drug candidates may not be predictive of the results we may obtain in later stage trials. The failure of clinical trials to demonstrate safety and efficacy of one or more of our drug candidates will have a material adverse effect on our business and financial condition **for any number of reasons including delays in development, additional unanticipated studies required by the FDA, or an ultimate inability to market a product candidate and generate a profit** . Delays in the commencement of clinical trials of our drug candidates could result in increased costs to us and delay our ability to generate revenues. Our drug candidates will require continued extensive clinical trials prior to the submission of a regulatory application for commercial sales. Because of the nature of clinical trials, we do not know whether future planned clinical trials will begin on time, if at all. Delays in the commencement of clinical trials could significantly increase our drug development costs and delay any commercialization of our drug candidates. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a drug candidate. ~~36The~~ **34The** commencement of clinical trials can be delayed for a variety of reasons, including delays in: ● demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial; ● convincing the FDA that we have selected valid endpoints for use in proposed clinical trials; ● reaching agreements on acceptable terms with prospective contract manufacturers for manufacturing sufficient quantities of our drug candidates; and ● obtaining institutional review board approval to conduct a clinical trial at a prospective site. In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Delays in the completion of, or the termination of, clinical trials of our drug candidates could result in increased costs to us and could delay or prevent us from generating revenues. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including: ● regulators or institutional review boards may not authorize us to commence or conduct a clinical trial at a prospective trial site; ● our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect may not be promising; ● we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; ● regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; ● the cost of our clinical trials may be greater than we currently anticipate and we may lack adequate funding to continue the clinical trial; ● the timing of our clinical trials may be longer than we currently anticipate; ● our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner (including delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials); ● inadequacy of or changes in our manufacturing process or compound formulation; ● slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates; ● the effects of our drug candidates may not be the desired effects or may include undesirable side effects or our drug candidates may have other unexpected characteristics; ● changes in applicable regulatory policies and regulations; ~~37~~ **35** ● delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites; ● uncertainty regarding proper dosing; ● failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise fail to perform their services in a timely or acceptable manner; ● scheduling conflicts with participating clinicians and clinical institutions; ● failure to construct appropriate clinical trial protocols; ● insufficient data to support regulatory approval; ● inability or unwillingness of medical investigators to follow our clinical protocols; and ● the timing of discussions and meetings with the FDA or other regulatory authorities regarding the scope or design of our clinical trials. Many of these factors that may lead to a delay, suspension or termination of clinical trials of our drug candidates may also ultimately lead to denial of regulatory approval of our drug candidates. From time to time, we may publicly announce our expected timing of completing certain milestones relating to various scientific, clinical, regulatory, development and other objectives related to our business. For example, these milestones may include the commencement or

completion of scientific studies or clinical trials or the submission or approval of regulatory filings. Our estimates for completion of these milestones are based on a variety of assumptions, some of which may be out of our control. If we experience delays in the completion of, or termination of, clinical trials of any drug candidates in the future, or if we do not meet our milestones within the estimated timeframes that we have publicly announced, our business, financial condition and the commercial prospects for our drug candidates could be materially adversely affected, and our ability to generate product revenues could be delayed or eliminated. In addition, our stock price could decline. If we are unable to obtain U. S. and / or foreign regulatory approval, we will be unable to commercialize our drug candidates. Our drug candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labeling, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the U. S. and in many foreign jurisdictions prior to the commercial sale of our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for our drug candidates, we face risks that: ● the drug candidate may not prove to be sufficiently efficacious; ● the drug candidate may not prove to be safe; ● the drug candidate may not be readily co- administered or combined with other drugs or drug candidates; ● the results may not confirm the positive results from earlier preclinical studies or clinical trials; ● the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and ● the FDA or other regulatory agencies may require us to carry out additional studies. ~~38We~~ **36We** have limited experience in conducting and managing later stage clinical trials necessary to obtain regulatory approvals, including approval by the FDA. However, this risk would be mitigated in the event the Company is successful entering into a co- development agreement with a pharma partner for late stage clinical development. The time required to complete clinical trials and for the FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product and affect reimbursement by third- party payors. These limitations may limit the size of the market for the product. We may also become subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the U. S. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates. **Even if we are successful in obtaining regulatory approval to market a drug candidate, we, and our third- party manufacturer (s) will be, subject to extensive regulation by the FDA. Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA, or an NDA supplement, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Drug products must also comply with applicable requirements, including monitoring and recordkeeping activities, manufacturing requirements, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct- to- consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug' s approved labeling, or off- label use, limitations on industry- sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may, in their independent professional medical judgment, prescribe legally available drugs for off- label uses, manufacturers typically may not market or promote such off- label uses.** In addition to regulations in the U. S., we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved. Whether or not we obtain FDA approval for a drug candidate, we must obtain the requisite approvals from regulatory authorities in non- U. S. countries prior to the commencement of clinical trials or marketing of our products in those countries. Certain countries outside of the U. S. have a process that requires the submission of a clinical trial application, much like an IND, prior to the commencement of human clinical trials. In the E. U., for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country' s requirements, clinical trial development may proceed in that country. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and other applicable regulatory requirements. To obtain regulatory approval of an investigational drug under E. U. regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the U. S., with the exception of, among other things, country- specific document requirements. Drugs can be authorized in the E. U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures. ~~The~~ **37The** EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E. U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the E. U., as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from

biotechnology processes, such as genetic engineering, or (ii) contain a new active substance indicated for the treatment of certain diseases. Changes in existing laws and regulations affecting the healthcare industry could increase our costs and otherwise adversely affect our business. Our research and development activities, preclinical studies and clinical trials, and the manufacturing, marketing and labeling of any products we may develop, are subject to extensive regulation by the FDA and other regulatory authorities in the U. S. and other countries. Changes in existing federal, state and foreign laws and agency regulations may be established that could prevent or delay regulatory approval of our drug candidates or materially increase our costs, including: ● changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our drug candidates; ~~39~~ ● new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; ● changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and ● changes in FDA and foreign current cGMP that would make it more difficult for us to manufacture our drug candidates in accordance with cGMP. Delays in obtaining or preventing our obtaining regulatory approval of our drug candidates could materially adversely affect our ability to commercialize any of our drug candidates and our ability to receive product revenues or to receive milestone payments or royalties from any product rights we might license to others. We rely on third parties to conduct clinical trials for our drug candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our drug candidates. We rely on independent contractors, including clinical research organizations, in certain areas that are particularly relevant to our research and drug development plans, such as for data management for the conduct of clinical trials. The competition for these relationships is intense, and we may not be able to maintain our relationships with them on acceptable terms. Independent contractors generally may terminate their engagements at any time, subject to notice. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time conducting research on and trials of our drug candidates and assisting in developing them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols or fail to meet expected deadlines, our clinical trials may need to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by our independent contractors or other outside parties, our drug candidate development costs will increase and we may not be able to attain regulatory approval for or successfully commercialize our drug candidates. In addition, we have no control over the financial health of our independent contractors. Several of our independent contractors are in possession of valuable and sensitive information relating to the safety and efficacy of our drug candidates, and several others provide services to a significant percentage of the patients enrolled in our clinical trials in which such independent contractors participate. Should one or more of these independent contractors become insolvent, or otherwise are not able to continue to provide services to us, the clinical trial in which such contractor participates could become significantly delayed and we may be materially adversely affected as a result of the delays and additional expenses associated with such event. ~~We~~ **38We** may not be able to obtain or maintain orphan drug exclusivity for our product candidates. Prexigebersen has received orphan drug designations for the treatment of AML in the U. S. Orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200, 000 people in the U. S. at the time of application for orphan designation. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan designation qualifies the sponsor of the product for a tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven- year exclusive marketing period in the U. S. for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, ~~a~~ **orphan drug exclusivity may not effectively protect the product candidate from competition for several reasons including different** ~~drug~~ **drugs** ~~that~~ **with different active ingredients may be approved for the same conditions and competitors also potentially could secure approval of the same drug for different non- orphan conditions. Even after an orphan drug is approved,** the FDA **can subsequently** ~~considers to be clinically superior to, or different from, the approved~~ **approve** ~~orphan drug, even though for~~ the same **drug** ~~indication, may also obtain approval in the U. S.~~ during the seven- year exclusive marketing period **for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care** . Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. **Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process. Orphan drug designation in no way ensures ultimate regulatory approval.** In October 2016, prexigebersen also received orphan drug designation for AML in the E. U. from the EMA. To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life- threatening or chronically debilitating rare condition with a prevalence of less than five in 10, 000 in the E. U. Orphan drug designation provides incentives designed to ~~40facilitate~~ -- **facilitate** development, including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the E. U. following product approval. There is no guarantee that any of our other drug candidates will receive orphan drug designation or that, even if such drug candidate is granted such status, the drug candidate' s clinical development and regulatory approval process will not be delayed or will be successful. Risks Related to Manufacturing Our Drug CandidatesWe rely on third parties for manufacturing of our clinical drug supplies; our dependence on these manufacturers may impair the development of our drug candidates. We have no ability to internally manufacture the drug candidates that we need to conduct our clinical trials. For the foreseeable future, we expect to continue to rely on third- party manufacturers and other third parties to produce, package and store sufficient quantities of our drug candidates and any future drug candidates for

use in our clinical trials. We have entered into agreements with third- party manufacturers for the manufacture of our drug requirements, including agreements for the manufacture of prexigebersen for use in our Phase 2 clinical trial in AML, as well as agreements for the manufacture of BP1002, BP1003 and BP1001- A for use in our Phase 1 clinical trials. To date, we have made steady progress with our current third- party manufacturers, overcoming challenges associated with scaling up manufacturing to develop their capabilities to supply us with our necessary quantities of drug supplies for our clinical trials. However, we may face various risks and uncertainties in connection with our reliance on third- party manufacturers, including: ● reliance on third- party manufacturers for regulatory compliance and quality assurance; ● the possibility of breach of the manufacturing agreement by the third- party manufacturer because of factors beyond our control; ● the possibility of termination or nonrenewal of our manufacturing agreement by the third- party manufacturer at a time that is costly or inconvenient for us; **39** ● the potential that third- party manufacturers will develop know- how owned by such third- party manufacturer in connection with the production of our drug candidates that is necessary for the manufacture of our drug candidates; and ● reliance on third- party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge. Our drug candidates are complicated and expensive to manufacture. If our third- party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development of our drug candidates. While we may be able to identify replacement third- party manufacturers or develop our own manufacturing capabilities for these drug candidates, this process would likely cause a delay in the availability of our drug candidates and an increase in costs. In addition, third- party manufacturers may have a limited number of facilities in which our drug candidates can be manufactured, and any interruption of the operation of those ~~41facilities~~ **facilities** due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates. We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities. There are underlying risks associated with the manufacture of our drug candidates, which have never been manufactured in large scale. Furthermore, we anticipate continued reliance on third- party manufacturers if we are successful in obtaining marketing approval from the FDA or other regulatory agencies for any of our drug candidates. To date, our drug candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials by third- party manufacturers, and have never been manufactured in large scale. Additionally, as in the development of any new compound, there are underlying risks associated with their manufacture. These risks include, but are not limited to, cost, process scale- up, process reproducibility, construction of a suitable process plant, timely availability of raw materials, as well as regulatory issues associated with the manufacture of an active pharmaceutical agent. Any of these risks may prevent us from successfully developing our drug candidates. Our failure, or the failure of our third- party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors and reliable product packaging for diverse environmental conditions, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially adversely affect our business and financial condition. If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third- party manufacturers to produce commercial quantities of such approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved drug candidates in a timely or economic manner, or at all. Significant scale- up of manufacturing may require additional validation studies, which the FDA or other regulatory authorities must review and approve. If our third- party manufacturers are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply. Identification of previously unknown problems with respect to a drug candidate ~~,~~ **and / or a commercial product (s) with which any of our candidates are being tested or a** manufacturer or facility **involved in the production of any such candidate or commercial product** may result in restrictions on the drug candidate, **product,** manufacturer or facility **that could have a material adverse effect on the development of our drug candidate (s)** . The FDA stringently applies regulatory standards for the manufacturing of our drug candidates. Identification of previously unknown problems with respect to a drug candidate, manufacturer or facility may result in restrictions on the drug candidate, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution. Any of the foregoing could have a material adverse effect on our business and financial condition **. 40In addition, because we are developing at least one of our drug candidates in combination with one or more third- party commercial products, we could also be subject to delays, difficulties, and other adverse effects if any such commercial products (or the companies and / or facilities involved in their marketing and / or production) experience safety, efficacy, compliance, or other issues. For example, one of the therapies with which BP1001 is being studied as a combination therapy candidate may have unexpected safety issues that are improperly attributed to BP1001, or the administration of BP1001 with such other therapies may result in safety issues or adverse events that may not have been present if such other therapies or BP1001 would have been used alone. And, the commercial drug (s) with which any of our candidates is being developed could become unavailable due to any number of circumstances beyond our control. This could delay or prevent our ability to complete the affected clinical studies and / or pursue, obtain, or maintain FDA approval, as applicable** . We may experience delays in the development of our drug candidates if the third- party manufacturers of our drug candidates cannot meet FDA requirements relating to current Good Manufacturing Practices. Our third- party manufacturers are required to produce our drug candidates under FDA cGMP in order to meet acceptable standards for our preclinical testing and clinical trials. If such standards change, the ability of third- party manufacturers to produce our drug candidates on the schedule we

require for our preclinical tests and clinical trials may be affected. In addition, third- party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our drug candidates. Any difficulties or delays in the manufacturing and supply of our drug candidates could increase our costs or cause us to lose revenue or postpone or cancel clinical trials. The FDA also requires that we demonstrate structural and functional comparability of a drug candidate produced by different third- party manufacturers. Because we may use multiple sources to manufacture our drug candidates, we may need to conduct comparability studies to assess whether manufacturing changes have affected the safety, identity, purity or potency of any drug candidate compared to the drug candidate produced by another manufacturer. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and significantly delay commercialization of our drug candidates. ~~42Risks~~ -- **Risks** Related to CommercializationIf we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue. We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drug candidates that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. If our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if any. Even if our drug candidates obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Factors that we believe could materially affect market acceptance of our drug candidates include: ● the timing of market introduction of competitive drugs; ● the demonstrated clinical safety and efficacy of our drug candidates compared to other drugs and other drug candidates; ● the suitability of our drug candidates to be co- administered or combined with other drugs or drug candidates; **41** ● the durability of our drug candidates in their ability to prevent the emergence of drug- resistant viral mutants; ● the convenience and ease of administration of our drug candidates; ● the existence, prevalence and severity of adverse side effects; ● other potential advantages of alternative treatment methods; ● the effectiveness of marketing and distribution support; ● the cost- effectiveness of our drug candidates; and ● the availability of reimbursement from managed care plans, the government and other third- party payors. If our approved drug candidates fail to achieve market acceptance, we would not be able to generate significant revenue. In addition, even if our approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if: ● new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete; ● unforeseen complications arise with respect to the use of our products; or ● sufficient third- party insurance coverage or reimbursement does not remain available. ~~43If~~ **Even if we receive regulatory approval of any product candidate or therapy that we may develop, we will be subject to ongoing regulatory obligations, reporting requirements and continued regulatory review, which may result in significant additional expenses. If we fail to comply with regulatory requirements or experience unanticipated problems with our products or product candidates, we may be subject to substantial penalties, fines, delays, suspensions, refusals and withdrawals of approvals. If BP1001 or any other product candidates that we are developing or may in the future are approved, they will be subject to ongoing regulatory requirements and reporting requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, recordkeeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including both federal and state requirements in the U. S. and requirements of comparable non- U. S. regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post- approval. Facilities of CMOs and testing laboratories are required to comply with extensive FDA, and non- U. S. regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases, current Good Tissue Practices (" cGTP "), regulations. As a result, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work with must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Additionally, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses and a company that is found to have improperly promoted off- label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations maybe enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. 42The FDA may seek consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers,**

manufacturing processes or testing laboratories, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: ● restrictions on our products, manufacturers or manufacturing processes; ● warning letters and untitled letters; ● civil penalties and criminal prosecutions and penalties; ● fines; ● injunctions; ● product seizures or detentions; ● import or export bans or restrictions; ● voluntary or mandatory product recalls and related publicity requirements; ● suspension or withdrawal of regulatory approvals; ● total or partial suspension of production; and ● refusal to approve pending applications for marketing approval of new products or of supplements to approved applications. If third- party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase. Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third- party payors, both in the U. S. and in foreign markets. Reimbursement by a third party may depend upon a number of factors, including the third- party payor' s determination that use of an approved drug candidate is: ● a covered benefit under its health plan; ● safe, effective and medically necessary; ● appropriate for the specific patient; ● cost effective; and ● neither experimental nor investigational. The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products vary widely from country to country. Some countries require approval of the sale price of a drug candidate before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, ~~prescription~~ **43prescription** pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the approved drug and negatively impact the revenues we are able to generate from the sale of the approved drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. Obtaining reimbursement approval for an approved drug from each third- party and government payor is a time- consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data for the use of any approved drug candidates to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third- party reimbursement for the use of any approved drug incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any approved drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the approved drugs and the clinical setting in which it is used, may be based on payments allowed for lower- cost products or combinations of products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and / or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the U. S. In the U. S., at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. While health care reform may increase the number of patients who have insurance coverage for the use of any approved drug, it may also include changes that adversely affect reimbursement for approved drugs. In addition, there has been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our drug candidates that obtain approval. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third- party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third- party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. ~~44Our~~ -- **Our** inability to promptly obtain coverage and profitable reimbursement rates from government- funded and private payors for any of our drug candidates that obtain approval could have a material adverse effect on our business and financial condition. Risks Related to Intellectual PropertyIf our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business. Our patent portfolio currently includes ~~five~~ **seven** issued patents in the U. S. and ~~17~~ **61** issued patents in foreign jurisdictions ~~: Claims Related to DNAbilize ® Patent No. Title Date Issued US 9, 744, 187 P- ethoxy nucleic acids for liposomal formulationAugust 29, 2017US 10, 335, 428 P- ethoxy nucleic acids for liposomal formulationJuly 2, 2019US 10, 898, 506 P- ethoxy nucleic acids for liposomal formulationJanuary 26, 2021SG 11201802718P P- ethoxy nucleic acids for liposomal formulationMay 12, 2021EA 038277 (in force in AM, AZ, BY, KG, KZ, RU, TJ, TM) P- ethoxy nucleic acids for liposomal formulationAugust 4, 2021AU 2016340123P- ethoxy nucleic acids for liposomal formulationJanuary 5, 2023MX 403603P- ethoxy nucleic acids for liposomal formulationJune 20, 2023IN 472686P- ethoxy nucleic acids for liposomal formulationNovember 24, 2023Compositions and Methods of Use for Specific Drug TargetsPatent No. Title Date Issued US 10, 927, 379 Combination therapy with liposomal antisense oligonucleotidesFebruary 23, 2021US 11, 041, 153 P- ethoxy nucleic acids for STAT3 inhibitionJune 22, 2021EP 3 512 525 (in force in DE, ES, FR, GB, and NL) Combination therapy with liposomal antisense oligonucleotidesJuly 27, 2022JP 7132911Combination therapy with liposomal antisense oligonucleotidesAugust 30, 2022JP 7186721P- ethoxy nucleic acids for IGF- 1R inhibitionDecember 1, 2022CN ZL 201880033244. 6P- ethoxy nucleic acids for STAT3 inhibitionDecember 16, 2022EA 041953 (in force in AM, AZ, BY, KG,~~

~~KZ, RU, TJ, TM) Combination therapy with liposomal antisense oligonucleotidesDecember 19, 202245JP 7237009P- ethoxy nucleic acids for STAT3 inhibitionMarch 2, 2023EA 042663 (in force in AM, AZ, BY, KG, KZ, RU, TJ, TM) P- ethoxy nucleic acids for STAT3 inhibitionMarch 9, 2023HK 400 11951Combination therapy with liposomal antisense oligonucleotidesApril 6, 2023JP 7284709P- ethoxy nucleic acids for BCL2 inhibitionMay 23, 2023EA 044637P- ethoxy nucleic acids for BCL2 inhibitionSeptember 19, 2023MX 408790P- ethoxy nucleic acids for STAT3 inhibitionDecember 7, 2023MX 408785P- ethoxy nucleic acids for BCL2 inhibitionDecember 7, 2023We~~ have ~~six~~ **three** additional pending patent applications in the U. S. and ~~seven~~ **five** additional allowed patent application in a foreign jurisdiction. Further, we have pending patent applications in key foreign jurisdictions across our six families of applications. Our success depends in large part on our ability to obtain and maintain patent protection both in the U. S. and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to ~~us~~ **44us**. Patent applications in the U. S. are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the USPTO for the entire time prior to issuance as a U. S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on, our drug candidates. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U. S. patent position. Furthermore, we may not have identified all U. S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market. The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different molecule, our patents may not prevent others from directly competing with us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the U. S. and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed. Because of the extensive time required for development, testing and regulatory review of a drug candidate, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period ~~46following~~ **following** commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our drug candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such drug candidates, those drug candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FDCA or trade secret protection. The Leahy- Smith America Invents Act (the " America Invents Act ") was signed into law in September 2011, and many of the substantive changes became effective in March 2013. The America Invents Act reforms U. S. patent law in part by changing the standard for patent approval from a " first to invent " standard to a " first to file " standard and developing a post-grant review system. This legislation changes U. S. patent law in a way that may weaken our ability to obtain patent protection in the U. S. for those applications filed after March 2013. If any third- party owners of intellectual property we may license in the future do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed. We may enter into licenses for third- party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. If applicable, our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of any such patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and financial condition. Because our research and development of drug candidates incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and complete our preclinical and clinical research and commercialize the drug candidates that result from this research. We expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay (i) annual maintenance fees until a drug candidate is sold for the first time, (ii) running royalties on net sales of drug candidates, (iii) minimum annual royalties after a drug candidate is sold for the first time, and (iv) one- time payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may

be obligated to pay ~~additional~~ **45additional** royalties, at specified rates, based on net sales of our drug candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include payment obligations such as milestone payments or minimum expenditures for research and development. We expect that any future licenses would contain reporting, insurance and indemnification requirements. If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Our research, development and commercialization activities, including any drug candidates resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, if issued, could be asserted against us. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development or manufacturing of drug candidate that is the subject of the suit. Further, if we are found to have infringed a third- party patent, we could be obligated to pay royalties and / or other payments to the third party related to our drug candidates, which may be substantial, or we could be enjoined from selling our drug candidates that obtain approval. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our drug candidates and technology. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business and financial condition. ~~47Litigation~~ -- **Litigation** regarding patents, intellectual property and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate. Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third- party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding: ● the patentability of our inventions relating to our drug candidates; and / or ● the enforceability, validity or scope of protection offered by our patents relating to our drug candidates. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may: ● incur substantial monetary damages; ● encounter significant delays in bringing our drug candidates to market; and / or ● be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, ~~during~~ **46during** the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property. We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. may be less willing to protect trade secrets. Costly ~~48and~~ -- **and** time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business and financial condition. **We may be subject to claims that our employees and contractors have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.** Risks Related to Our SecuritiesRaising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights. Additionally, sales of a substantial number of shares of our common stock or other securities in the public market could cause our stock price to fall. We expect to seek the additional capital necessary to fund our operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. To

the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us. In addition, sales of a substantial number of shares of our common stock or other securities in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We may issue additional shares of our common stock in accordance with our equity incentive plans or upon exercise or conversion of outstanding securities that are exercisable for or convertible into shares of our common stock, which may cause dilution to existing stockholders. As of December 31, ~~2023~~ **2024** , there were ~~43~~ **96** , ~~383~~ **389** shares of common stock reserved for issuance upon the exercise of outstanding options granted under our equity incentive plans. As of December 31, ~~2023~~ **2024** , there were (i) ~~937~~ **921** additional shares of common stock reserved for future issuance of awards under the Bio- Path Holdings, Inc. 2017 Stock Incentive Plan, as amended (the " 2017 Stock Incentive Plan "), and (ii) ~~53~~ **1** , ~~950~~ **200, 948** additional shares of common stock reserved for future issuance of awards under the Bio- Path Holdings, Inc. 2022 Stock Incentive Plan (the " 2022 Stock Incentive Plan "). In addition, as of December 31, ~~2023~~ **2024** , there were ~~190~~ **4716** , ~~063~~ **490, 014** shares of common stock reserved for issuance upon the exercise of outstanding warrants that we have issued in connection with prior securities offerings. To the extent that outstanding stock options and warrants are exercised, existing stockholders' ownership interests may be diluted, which may reduce the market price of our common stock. The trading price of our common stock has been volatile and is likely to be volatile in the future. The trading price of our common stock has been highly volatile. From January 1, 2020 through December 31, ~~2023~~ **2024** , our stock price has fluctuated from a low of $ ~~6~~ **0** . ~~40~~ **59** to a high of $ 486. 80, after adjustment for reverse stock splits. The market price for our common stock will be affected by a number of factors, including: ● the denial or delay of regulatory approvals of our drug candidates or receipt of regulatory approval of competing products; ● our ability to accomplish clinical, regulatory and other drug development milestones; ● the ability of our drug candidates, if they receive regulatory approval, to achieve market success; ● the performance of third- party manufacturers and suppliers; ● developments with respect to patents and other intellectual property rights; ● sales of common stock or other securities by us or our stockholders in the future; ● additions or departures of key scientific or management personnel; ~~49~~ ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates; ● trading volume of our common stock; ● investor perceptions about us and our industry; ● public reaction to our press releases, other public announcements and SEC and other filings; ● the failure of analysts to cover us, or changes in analysts' estimates or recommendations; ● the failure by us to meet analysts' projections or guidance; ● general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and ● the other factors described elsewhere in this " Item 1A. Risk Factors " or the section titled " Risk Factors " contained in our other public filings. The stock prices of many companies in the biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company' s securities, securities class action litigation often has been initiated against a company. If any class action litigation is initiated against us, we may incur substantial costs and our management' s attention may be diverted from our operations, which could materially adversely affect our business and financial condition. **48Our common stock has been delisted from The Nasdaq Capital Market and there is no guarantee that our common stock will be regularly traded on the OTCQB Venture Market or other over- the- counter markets. On February 14, 2025, Nasdaq notified the Company that the Panel determined to delist the Company' s common stock. On February 19, 2025, trading of our common stock was suspended on The Nasdaq Capital Market and trading of our common stock commenced on the OTCQB Venture Market under the ticker symbol " BPTH. " The OTCQB Venture Market is a significantly more limited market than The Nasdaq Capital Market, and quotation on the OTC Venture Market has resulted in a less liquid market for existing and potential holders of our common stock which could further depress the trading price of our common stock. There is no guarantee that our common stock will continue to be traded on the OTCQB Venture Market or on other over- the- counter markets, and accordingly, our common stock may become illiquid. We can provide no assurance as to whether broker- dealers will continue to provide public quotes of the common stock on the OTCQB Venture Market, or whether the trading volume of the common stock will be sufficient to provide for an efficient trading market.** Our common stock is thinly traded and in the future may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares. To date, we have a low volume of daily trades in our common stock ~~on The Nasdaq Capital Market~~ . Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders. The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the foreseeable future. As noted above, our common stock may be sporadically and / or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. Our certificate of incorporation grants our Board of Directors the power to designate and issue additional shares of common and / or preferred stock. Our authorized capital consists of 200, 000, 000 shares of common stock and 10, 000, 000 shares of preferred stock. Our preferred stock may be designated into series pursuant to authority granted by our certificate of incorporation, and on approval from our Board of Directors (the " Board "). The Board, without any action by our stockholders, may designate and issue shares in such classes or series as the Board deems appropriate and establish the rights, preferences and privileges of such shares, including dividends, liquidation and voting rights. The rights of holders of other classes or series of stock that may be issued

could be superior to the rights of holders of our common shares. The designation and issuance of shares of capital stock having preferential rights could adversely affect other rights appurtenant to shares of our common stock. We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us. We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. ~~50~~ **Our management is required to devote substantial time and incur additional expense to comply with public company regulations. As a public reporting company, we are subject to the Sarbanes- Oxley Act of 2002, as well as to the information and reporting requirements of the SEC and other federal securities laws. We are also subject to the rules of the OTCQB Venture Market. As a result, we incur significant legal, accounting, and other expenses that we would not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. Compliance with these public company obligations places significant additional demands on our limited number of finance and accounting staff and on our financial, accounting and information systems. 49**