

GLOBAL PHARMA LABS, INC. RISK FACTORS

Please consider the following risk factors and other information in this offering circular relating to our business before deciding to invest in our common stock.

This offering and any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the information contained in this offering circular before deciding whether to purchase our common stock. If any of the following risks actually occur, our business, financial condition and results of operations could be harmed. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment.

We consider the following to be the material risks for an investor regarding this offering. Our company should be viewed as a high-risk investment and speculative in nature. An investment in our common stock may result in a complete loss of the invested amount.

An investment in our common stock is highly speculative, and should only be made by persons who can afford to lose their entire investment in us. You should carefully consider the following risk factors and other information in this report before deciding to become a holder of our common stock. If any of the following risks actually occur, our business and financial results could be negatively affected to a significant extent.

Risks:

We have incurred significant losses since our inception, anticipate that we will incur substantial and increasing losses for the foreseeable future, and may never achieve or maintain profitability.

We are a pre-clinical stage biopharmaceutical company with a limited operating history. Since inception, we have focused our efforts primarily on developing OA-sys, with the goal of achieving regulatory approval. Since inception, we have incurred operating losses. To date, we have not received regulatory approvals for any of our product candidates or generated any revenue from the sale of products, and we do not expect to generate any revenue in the foreseeable future. We expect to continue to incur substantial and increasing expenses and operating losses over the next several years, as we continue to develop OA-sys, and our other current and future product candidates. In addition, we expect to incur significant sales, marketing, and manufacturing expenses related to the commercialization of OA-sys, and our other current and future product candidates, if they are approved by the U.S. Food and Drug Administration (“FDA”) or such an equivalent in any other jurisdiction. As a result, we expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- conduct our pre-clinical trial with OA-sys for the treatment of the symptoms of pain, stiffness, and loss of function associated with OA.
- initiate and enroll patients in our pre-clinical trials in other indications for OA-sys;
- in-license or acquire additional product candidates;
- conduct early stage clinical trials for any product candidates that successfully complete proof of concept studies;
- seek regulatory approval for any product candidates that successfully complete late-stage clinical trials;
- conduct additional non-clinical studies with any product candidates;

- conduct preclinical studies with OA-sys or any additional product candidates;
- increase manufacturing batch sizes of OA-sys to satisfy FDA requirements and/or the requirements of other jurisdictions for a marketing application submission;
- establish a sales, marketing, and distribution infrastructure, and scale up external manufacturing capabilities to commercialize any products for which we may obtain regulatory approval and that we choose not to license to a third party;
- require larger quantities of product;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical, quality control, and scientific personnel;

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, potentially entering into collaboration and license agreements, obtaining regulatory approval for product candidates and manufacturing, marketing, and selling any products for which we may obtain regulatory approval, achieving market acceptance of our products, satisfying any post-marketing requirements, maintaining appropriate distribution, setting prices, and obtaining reimbursement for our products from private insurance or government payors. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we may incur or when, or if, we will be able to achieve profitability. If we are required by the FDA or comparable foreign regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need additional funding to conduct our future clinical trials and to complete development and commercialization of our product candidates. Even if this offering is successful, if we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Conducting clinical trials, pursuing regulatory approvals, establishing outsourced manufacturing relationships and successfully manufacturing and commercializing our product candidates, including OA-sys, is, and will be, a very time-consuming, expensive, and uncertain process that takes years to complete. We will need to raise additional capital to:

- fund our future clinical trials for our current product candidates, especially if we encounter any unforeseen delays or difficulties in our planned development activities;
- fund our operations and continue our efforts to hire additional personnel and build a commercial infrastructure to prepare for the commercialization of OA-sys, and our other current and future product candidates, if approved by the FDA and/or the FDA equivalent in other jurisdictions;
- qualify and outsource the commercial-scale manufacturing of our products under current good manufacturing practices, or cGMP;

- develop additional product candidates, and
- in-license other product candidates.

We may not have sufficient financial resources to meet all of our objectives if OA-sys is approved, which could require us to postpone, scale back, or eliminate some, or all, of these objectives, including our potential launch activities relating to OA-sys. Our future funding requirements will depend on many factors, including, but not limited to:

- the potential for delays in our efforts to seek regulatory approval for OA-sys, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market, and distribute OA-sys;
- the rate of progress and costs related to our Phase 1 development of OA-sys;
- the rate of progress and costs of our efforts to prepare for the submission of a new drug application, or NDA, for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical or preclinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the cost and timing of manufacturing sufficient supplies of OA-sys in preparation for commercialization;
- the effect of competing technological and market developments;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates;
- the terms and timing of any collaborative, licensing, co-promotion, or other arrangements that we may establish; and
- the success of the commercialization of OA-sys, and any other of our current or future product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional businesses, products, and technologies. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, royalties, and corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs or our commercialization efforts.

We have a limited operating history and no history of commercializing products, which may make it difficult to evaluate our business and prospects.

We commenced operations in 2016, and our operations to date have been limited to organizing and staffing our company, business planning, and developing our product candidates, including undertaking further analysis of preclinical studies and further analysis of proof of concept clinical trials of our lead product candidate, OA-sys. We have not yet demonstrated an ability to obtain regulatory approval for, or successfully commercialize, a product candidate. In addition we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown difficulties. If our product candidates are approved by the FDA or by the FDA equivalent in any other jurisdiction, we will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

A conflict of interest may arise between our CEO, Mr. Sylvester Crawford's interest in selling shares for his own benefit and his interest in selling shares on the Company's behalf.

The Company may be negatively affected if Mr. Crawford's decides to prioritize the sale of his shares rather than those of the Company since the Company will not receive any proceeds from the sale of his shares. There may not be enough interest from investors in purchasing the Company's shares if investors decide that the sale of Mr. Crawford's shares could undercapitalize the Company. The sale of Mr. Crawford's shares before the sale of Company shares may signal lack of internal confidence in the Company to investors.

- 7 -

[Table of Contents](#)

We are substantially dependent on the success of our lead product candidate, OA-sys and cannot guarantee that this product candidate will successfully complete our planned clinical trials, receive regulatory approval, or be successfully commercialized.

We currently have no products approved for commercial distribution. We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, OA-sys. Our business depends entirely on the successful development and commercialization of our product candidates, and in particular, OA-sys, which may never occur. Our ability to generate revenues in the near term is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize OA-sys. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product.

Our lead product candidate, OA-sys, will require clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we generate any revenues from product sales. We plan to initiate our clinical trials with OA-sys for the treatment of pain, stiffness, and loss of function in patients with OA by July 2018. However, we cannot assure you that we will meet this timeline.

We are not permitted to market or promote any of our product candidates, including OA-sys, before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Even if OA-sys is approved, they may be subject to limitations on the indicated uses for which it may be marketed, distribution restrictions, or to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products. If we do not receive FDA approval or the approval of an offshore jurisdiction for, and successfully commercialize, OA-sys, we will not be able to generate revenue from these product candidates in the United States or in any other jurisdiction in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing OA-sys will have a material adverse impact on our business and financial condition.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that OA-sys, or any other of our current or future product candidates will be successful in clinical trials or receive regulatory approval. In addition, we have not submitted an IND for OA-sys and have only completed proof of concept studies. Furthermore, our product candidate OA-sys is only in the early stages of product development and additional preclinical work is required before we may submit an IND and begin clinical trials.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue will be materially impaired.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical

development and may vary among jurisdictions, and may require us to amend our clinical trial protocols or conduct additional studies that require regulatory or institutional review board, or IRB, approval, or otherwise cause delays in the approval or rejection of an application. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates, including OA-sys or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any of our collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA, and similar regulatory authorities outside the United States and Europe. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations, or CROs, and consultants to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced.

We may also experience numerous unforeseen events during, or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs. For instance, as symptoms of OA are also consistent with other disease which may spontaneously resolve on its own, our studies in recently diagnosed patients may fail to show a treatment effect;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- we, the regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being

exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;

- changes in marketing approval policies during the development period rendering our data insufficient to obtain marketing approval;
- changes in or the enactment of additional statutes or regulations;
- changes in regulatory review for each submitted product application;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of an NDA;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may decide, or regulators may require us, to conduct additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs.
- we may fail to reach an agreement with regulators regarding the scope or design of our clinical trials;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the study or clinical trial or extend the study's or clinical trial's duration;
- there may be regulatory questions regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our study design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks. For instance, in our communications with the FDA, the FDA has raised questions and had comments regarding our preclinical and clinical studies, such as comments on the acceptability of the proposed trial designs for our product candidates, the number of patients planned for our studies, our data analysis plans, the species and doses used in our preclinical studies, and the results of our preclinical studies;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications. For instance, the FDA may raise questions regarding the relevance of only studying knee OA.
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Moreover, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these trials or tests are not positive, or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired or are not covered by our intellectual property;
- obtain approval with labeling that includes significant use or distribution restrictions, including restrictions on the intended patient population, or safety warnings, including boxed warnings, contraindications, and precautions, or may not include label statements necessary or desirable for successful commercialization;
- be subject to additional post-marketing testing and surveillance requirements, including REMS; or
- have the product removed from the market after obtaining marketing approval.

Our product candidate development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors, or the competitors of our collaborators, to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, such delays may ultimately lead to the denial of marketing approval of any of our product candidates. If any of this occurs, our business, financial condition, results of operations, and prospects will be materially harmed.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Furthermore, there is the possibility that the FDA has not previously reviewed product candidates for the indications we are pursuing, such as anti-infectives for the treatment of OA pain, stiffness, and loss of function. As a result, we may experience delays in regulatory approval due to uncertainties in the approval process.

Finally, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications or uses than we request, may contain significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval

contingent on the performance of costly post-marketing clinical trials, surveillance, or other requirements, including REMS to monitor the safety or efficacy of the product, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for our product candidates.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate will be materially impaired.

- 8 -

[Table of Contents](#)

The FDA may determine that OA-sys, or any other of our current or future product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, if concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical or preclinical testing, the FDA may order us to cease further development, decline to approve the drug or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug.

The number of requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by OA-sys, or any other of our current or future product candidates could also result in denial of regulatory approval by the FDA or other comparable foreign authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of OA-sys, or any other of our current or future product candidates.

If any of our other product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed in those jurisdictions.

In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval by the FDA may differ substantially from that required to obtain approval by other jurisdictions. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA or its equivalent in another country does not ensure approval by regulatory authorities in all countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

In the future we may face significant competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Our operating results will suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of pain and central nervous system disorders. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Specifically, there are a large number of companies developing or marketing therapies for the treatment and management of pain, including the pain of osteoarthritis. Among the companies that currently market or are developing therapies that, if approved, our product candidates would potentially compete with include: Alkermes plc; Allergan plc; Carbylan Therapeutics, Inc.; Eli Lilly and Company; Flexion Therapeutics, Inc.; Grunenthal GmbH; Janssen Research & Development, LLC; Levolta Pharmaceuticals, Inc.; Merrion Pharmaceuticals plc; Otsuka Pharmaceutical Co. Ltd.; Thar Pharmaceuticals, Inc.; and Transition Therapeutics Inc.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

We are not aware of any generic products currently available on the market that are approved for the specific indications that we are pursuing; however, generic forms of the active ingredients of our product candidates could be used off-label. Any such off-label use could adversely affect our profitability and have a negative effect on our operating results and financial condition.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, we may be unable to generate product revenues.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of pharmaceutical products. If approved, in order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. If one of our product candidates is approved by the FDA, we plan to build a commercial infrastructure, including the creation of a specialty sales force to launch that product candidate throughout the United States. In the future, we may seek to further penetrate the U.S. market by expanding our sales force or through collaborations with other pharmaceutical or biotechnology companies or third-party manufacturing and sales organizations. If approved for marketing outside the United States, we intend to commercialize our product candidates outside the United States with a marketing and sales collaborator or collaborators, and with our own sales force.

We have no prior experience in the marketing, sale, and distribution of pharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of our own sales force and related compliance plans to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our future collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing and sales personnel. In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize OA-sys, or any other of our current or future product candidates, which would limit our ability to generate product revenues. Factors that may inhibit our efforts to commercialize OA-sys, or any other of our current or future product candidates on our own include:

- our inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe OA-sys, or any other of our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;

- the clinical indications for which the product is approved;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Although our current plan is to hire most of our sales and marketing personnel only if a product candidate is approved by the FDA or the FDA equivalent in another jurisdiction, we will incur expenses prior to product launch in recruiting this sales force and developing a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA requirements or requirements by the FDA equivalent in another jurisdiction or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing OA-sys, or any other of our current or future product candidates.

In the event we are unable to collaborate with a third-party marketing and sales organization to commercialize any approved product candidates outside the United States, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

- 9 -

[Table of Contents](#)

We will rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements.

We will rely on third-party CROs to conduct, supervise, and monitor our preclinical and clinical trials for our product candidates, including OA-sys, and do not currently plan to independently conduct clinical or preclinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities and adversely affect our business.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our preclinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical trials are conducted in accordance with good laboratory practice, or GLP, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording, and reporting the results of preclinical and clinical trials

to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs, we or our CROs may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials.

In addition, once we have an approved product, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical or clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

Our CROs may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

If the manufacturers upon whom we rely fail to produce our product candidates in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our product candidates, but we may do so in the future. We currently outsource all manufacturing of our product candidates to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our product candidates. Moreover, we do not yet have agreements established regarding commercial supply of our product candidates, and we may not be able to establish or maintain commercial manufacturing arrangements on

commercially reasonable terms for OA-sys, or any other of our current or future product candidates for which we obtain approval in the future.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our existing or future product candidates and programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. For example, our manufacturers will need to produce specific batches of our product candidates to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our contract manufacturers will need to demonstrate to the FDA and other regulatory authorities that this is acceptable stability data for our product candidates, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize OA-sys, or any of our other current or future product candidates. Furthermore, if our commercial manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

We only have one contract manufacturer for OA-sys for use in our preclinical trials. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. Our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials and for commercial use, if approved, would be jeopardized.

In addition, all manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA that are applicable to both finished drug products and active pharmaceutical ingredients used both for clinical and commercial supply, through its facilities inspection program. Our manufacturers must be approved by the FDA or its equivalent in other jurisdictions pursuant to inspections that will be conducted upon our submission of our marketing applications to the agency. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with our specifications, these cGMP requirements and with other FDA, state, and foreign regulatory requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, including imprisonment, suspension or restrictions of production, suspension, delay or denial of product approval or supplements to approved products, clinical holds or termination

of clinical studies, warning or untitled letters, regulatory authority communications warning the public about safety issues with the drug, refusal to permit the import or export of the products, product seizure, detention, or recall, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our current or future product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

- 10 -

[Table of Contents](#)

We are dependent upon our license agreement with our Chief Executive Officer related to the development of our current product candidates, and if the agreement is terminated for any reason our business will be materially harmed.

On November 22, 2016 we entered into an exclusive license agreement with Mr. Sylvester Crawford, our CEO. We were granted exclusive licenses to develop, manufacture, and commercialize Mr. Crawford's patents and applications related to the development of OA-sys, a product candidate that is currently in early stage development, anywhere in the world for human therapeutic and diagnostic use. Pursuant to the agreement, we are required to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize OA-sys. Under the terms of the agreements, we are required to pay Mr. Crawford a royalty equal to 1.5% of net sales of products containing the licensed technology by us, our affiliates, or permitted sublicensees. Unless earlier terminated by a party for cause or by us for convenience, the agreements remain in effect on a product-by-product and country-by-country basis until the later to occur of (1) the applicable product is no longer covered by a valid claim in that country or (2) 10 years from the first commercial sale of the applicable product in that country. Upon expiration of the agreements with respect to a product in a country, our license grant for that product in that country will become a fully paid-up, royalty-free, perpetual non-exclusive license. If Mr. Crawford terminates any of the agreements for cause, or if we exercise our right to terminate any of the agreements for convenience, the rights granted to us under such terminated agreement will revert to Mr. Crawford. To date, we have not been required to make any payments to Mr. Crawford under the license agreement. If the license agreement with Mr. Crawford is terminated for any reason, our business, financial condition, results of operations, and prospects will be materially harmed.

It is difficult and costly to protect our proprietary rights and as a result we may not be able to ensure their protection. In addition, patents have a limited lifespan and will eventually expire.

Market exclusivity awarded by the FDA upon the approval of an NDA is limited in scope and duration. Our commercial success will depend in part on obtaining, maintaining, enforcing, and defending against third-party challenges, our patent and trade secret protection for OA-sys, and any other of our current and future product candidates that we may develop, license, or acquire, and the related manufacturing methods. We will only be able to fully protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, should we enter into additional collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance, and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent

laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the patent application process is also subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting OA-sys, or any other of our current or future product candidates that we may develop, license or acquire by obtaining and defending patents.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a preclinical biopharmaceutical company, we are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Act, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act), the Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, and refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Our independent registered public accounting firm, MaloneBailey, LLP has issued a going concern opinion in their audit report in regards to our operations.

In their audit report our PCAOB auditor MaloneBailey, LLP issued a going concern opinion in regards to our operations. The going concern was issued due to the fact we have suffered a net loss and do not have a source of revenue sufficient to cover our operations which raises substantial doubt about our ability to continue.

We are a start-up stage company. Our ability to continue as a going concern is dependent upon our ability to commence a commercially viable operation and to achieve profitability. Since our inception we have generated only minor revenues, and currently have only limited operations, as we are presently in the planning stage of our business development. These factors raise substantial doubt about our ability to continue as a going concern. We may not be able to generate revenues in the future and as a result the value of our common stock may become worthless. There are no assurances that we will be successful in raising additional capital or successfully developing and commercializing our products and becoming profitable.

We may need to raise additional financing to support our operations, but we cannot be sure that we will be able to obtain additional financing on terms favorable to us when needed. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.

We have limited financial resources. There can be no assurance that we will be able to obtain financing to fund our operations in light of factors beyond our control such as the market demand for our securities, the state of financial markets, generally, and other relevant factors. Furthermore, there is no assurance that we will not incur debt in the future, that we will have sufficient funds to repay any future indebtedness or that we will not default on our future debts, which would thereby jeopardize our business viability. We may not be able to borrow or raise additional capital in the future to meet our needs, which might result in the loss of some or all of your investment in our common stock. Even if we do raise sufficient capital and generate revenues to support our operating expenses, there can be no assurance that the revenue will be sufficient to enable us to develop our business to a level where it will generate profits and cash flows from operations, or provide a return on investment. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, the newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders and the trading price of our Common Stock could be adversely affected. Further, if we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we are unable to continue as a going concern, you may lose your entire investment.

Our success depends substantially on the continuing efforts of our key personnel, and our business may be severely disrupted if we lose their services.

Our future success heavily depends upon the continued services of our key personnel. If one or more of our executives are unable or unwilling to continue in their present positions, it could disrupt our business operations, and we may not be able to replace them easily or at all.

Because we are small and do not have much capital, our marketing campaign may not be enough to attract sufficient clients to operate profitably. If we do not make a profit, we will suspend or cease operations.

Due to the fact we are small and do not have much working capital at present, we must limit our marketing activities and may not be able to make our product known to potential customers. Because we will be limiting our marketing activities, we may not be able to attract enough customers to operate profitably. If we cannot operate profitably, we may have to suspend or cease operations.

If we do not make a substantive profit, we may have to suspend or cease operations.

Because we are small and do not have much capital, we must limit the marketing of our website. Because we will be limiting our marketing activities, we may not be able to attract enough suppliers and customers to operate profitably. If we cannot operate profitably, we may have to suspend or cease operations.

Our internal controls may be inadequate, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. As defined in Exchange Act Rule 13a-15(f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in

accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and/or directors of the Company; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Our internal controls may be inadequate or ineffective, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public. Investors relying upon this misinformation may make an uninformed investment decision. If we cannot provide reliable financial reports, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock, if a market ever develops, could drop significantly and result in a loss of some or all of your investment.

We expect our quarterly financial results to fluctuate.

We expect our net sales and operating results to vary significantly from quarter to quarter due to a number of factors, including changes in:

- Demand for our products;
- Our ability to retain grow our business and attract new customers;
- General economic conditions;
- Advertising and other marketing costs;

As a result of the variability of these and other factors, our operating results in future quarters may be below the expectations of public market analysts and investors.

Our future success is dependent on our implementation of our business plan. We have many significant steps still to take.

Our success will depend in large part in our success in achieving several important steps in the implementation of our business plan, including the following: effectively marketing our website, identifying suitable electronic goods for purchase and subsequent resale, and forging lasting relationships with distributors. If we are not successful, we will not be able to fully implement or expand our business plan.

The recently enacted JOBS Act will allow the Company to postpone the date by which it must comply with certain laws and regulations intended to protect investors and to reduce the amount of information provided in reports filed with the SEC.

The recently enacted JOBS Act is intended to reduce the regulatory burden on “emerging growth companies”. The Company meets the definition of an “emerging growth company” and so long as it qualifies as an “emerging growth company,” it will, among other things:

-be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that its independent registered public accounting firm provide an attestation report on the effectiveness of its internal control over financial reporting;

-be exempt from the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of The Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”) and certain disclosure requirements of the Dodd-Frank Act relating to compensation of Chief Executive Officers;

-be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and instead provide a reduced level of disclosure concerning executive compensation; and

-be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board (the “PCAOB”) requiring mandatory audit firm rotation or a supplement to the auditor’s report on the financial statements.

Although the Company is still evaluating the JOBS Act, it currently intends to take advantage of all of the reduced regulatory and reporting requirements that will be available to it so long as it qualifies as an “emerging growth company”. The Company has elected not to opt out of the extension of time to comply with new or revised financial accounting standards available under Section 102(b)(1) of the JOBS Act. Among other things, this means that the Company’s independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of the Company’s internal control over financial reporting so long as it qualifies as an “emerging growth company”, which may increase the risk that weaknesses or deficiencies in the internal control over financial reporting go undetected. Likewise, so long as it qualifies as an “emerging growth company”, the Company may elect not to provide certain information, including certain financial information and certain information regarding compensation of executive officers, which would otherwise have been required to provide in filings with the SEC, which may make it more difficult for investors and securities analysts to evaluate the Company. As a result, investor confidence in the Company and the market price of its common stock may be adversely affected.

Notwithstanding the above, we are also currently a “smaller reporting company”, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$75 million and annual revenues of less than \$50 million during the most recently completed fiscal year. In the event that we are still considered a “smaller reporting company”, at such time as we cease being an “emerging growth company”, the disclosure we will be required to provide in our SEC filings will increase, but will still be less than it would be if we were not considered either an “emerging growth company” or a “smaller reporting company”. Specifically, similar to “emerging growth companies”, “smaller reporting companies” are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, being required to provide only two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as an “emerging growth company” or “smaller reporting company” may make it harder for investors to analyze the Company’s results of operations and financial prospects.

We are an “emerging growth company” under the JOBS Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates.

We will remain an “emerging growth company” for up to five years, although we will lose that status sooner if our revenues exceed \$1 billion, if we issue more than \$1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds \$700 million.

As we are a publicly reporting company, we will continue to incur significant costs in staying current with reporting requirements. Our management will be required to devote substantial time to compliance initiatives. Additionally, the lack of an internal audit group may result in material misstatements to our financial statements and ability to provide accurate financial information to our shareholders.

Our management and other personnel will need to devote a substantial amount of time to compliance initiatives to maintain reporting status. Moreover, these rules and regulations, which are necessary to remain as an SEC reporting Company, will be costly as an external third party consultant(s), attorney, or firm, may have to assist in some regard to following the applicable rules and regulations for each filing on behalf of the company.

We currently do not have an internal audit group, and we will eventually need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to have effective internal controls for financial reporting. Additionally, due to the fact that our officers and Director, have limited experience as an officer or Director of a reporting company, such lack of experience may impair our ability to maintain effective internal controls over financial reporting and disclosure controls and procedures, which may result in material misstatements to our financial statements and an inability to provide accurate financial information to our stockholders.

Moreover, if we are not able to comply with the requirements or regulations as an SEC reporting company, in any regard, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

We may never have a public market for our common stock or may never trade on a recognized exchange. Therefore, you may be unable to liquidate your investment in our stock.

There is no established public trading market for our securities. Our shares are not and have not been listed or quoted on any exchange or quotation system.

In order for our shares to be quoted, a market maker must agree to file the necessary documents with the National Association of Securities Dealers, which operates the OTCQB. In addition, it is possible that such application for quotation may not be approved and even if approved it is possible that a regular trading market will not develop or that if it did develop, will be sustained. In the absence of a trading market, an investor may be unable to liquidate their investment.

We may in the future issue additional shares of our common stock, which may have a dilutive effect on our stockholders.

Our Certificate of Incorporation authorizes the issuance of 100,000,000 shares of common stock, of which 50,500,000 shares are issued and outstanding as of January 26, 2017. The future issuance of our common shares may result in substantial dilution in the percentage of our common shares held by our then existing stockholders. We may value any common stock issued in the future on an arbitrary basis. The issuance of common stock for future services or acquisitions or other corporate actions may have the effect of diluting the value of the shares held by our investors, and might have an adverse effect on any trading market for our common stock.

We may issue shares of preferred stock in the future that may adversely impact your rights as holders of our common stock.

Our Certificate of Incorporation authorizes us to issue up to 20,000,000 shares of preferred stock. Accordingly, our board of directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval.

Our preferred Stock does not have any dividend, conversion, liquidation, or other rights or preferences, including redemption or sinking fund provisions. However, our board of directors could authorize the issuance of a series of

preferred stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends are declared to holders of our common stock, and the right to the redemption of such preferred shares, together with a premium, prior to the redemption of the common stock. To the extent that we do issue such additional shares of preferred stock, your rights as holders of common stock could be impaired thereby, including, without limitation, dilution of your ownership interests in us. In addition, shares of preferred stock could be issued with terms calculated to delay or prevent a change in control or make removal of management more difficult, which may not be in your interest as holders of common stock.

We do not currently intend to pay dividends on our common stock and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our common stock and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future and the success of an investment in shares of our common stock will depend upon any future appreciation in its value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

We may be exposed to potential risks resulting from requirements under Section 404 of the Sarbanes-Oxley Act of 2002.

As a reporting company we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. We do not have a sufficient number of employees to segregate responsibilities and may be unable to afford increasing our staff or engaging outside consultants or professionals to overcome our lack of employees.

We do not currently have independent audit or compensation committees. As a result, our directors have the ability, among other things, to determine their own level of compensation. Until we comply with such corporate governance measures, regardless of whether such compliance is required, the absence of such standards of corporate governance may leave our stockholders without protections against interested director transactions, conflicts of interest and similar matters and investors may be reluctant to provide us with funds necessary to expand our operations.

The costs to meet our reporting and other requirements as a public company subject to the Exchange Act of 1934 is and will be substantial and may result in us having insufficient funds to expand our business or even to meet routine business obligations.

As a public entity, subject to the reporting requirements of the Exchange Act of 1934, we will continue to incur ongoing expenses associated with professional fees for accounting, legal and a host of other expenses for annual reports and proxy statements. We estimate that these costs will range up to \$35,000 per year for the next few years and will be higher if our business volume and activity increases. As a result, we may not have sufficient funds to grow our operations.

Investors cannot withdraw funds once invested and will not receive a refund.

Investors do not have the right to withdraw invested funds. Subscription payments will be paid to Global Pharma Labs, Inc. and held in our corporate bank account if the Subscription Agreements are in good order and the Company accepts the investor's investment. Therefore, once an investment is made, investors will not have the use or right to return of such funds.

Our President, CEO and Director, Sylvester L. Crawford does not have any prior experience conducting a best effort offering, and our best effort offering does not require a minimum amount to be raised. As a result, we may not be able to raise enough funds to commence and sustain our business and our investors may lose their entire investment.

Sylvester L. Crawford does not have any experience conducting a best-efforts offering. Consequently, we may not be able to raise the funds needed to further business operations. Also, the best efforts offering does not require a minimum amount to be raised. If we are not able to raise sufficient funds, we may not be able to fund our operations as planned, and our business will suffer and your investment may be materially adversely affected. Our inability to successfully conduct a best-efforts offering could be the basis of your losing your entire investment in us.

The trading in our shares will be regulated by the Securities and Exchange Commission Rule 15G-9 which established the definition of a “Penny Stock.”

The shares being offered are defined as a penny stock under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), and rules of the Commission. The Exchange Act and such penny stock rules generally impose additional sales practice and disclosure requirements on broker-dealers who sell our securities to persons other than certain accredited investors who are, generally, institutions with assets in excess of \$4,000,000 or individuals with net worth in excess of \$1,000,000 or annual income exceeding \$200,000 (\$300,000 jointly with spouse), or in transactions not recommended by the broker-dealer. For transactions covered by the penny stock rules, a broker dealer must make certain mandated disclosures in penny stock transactions, including the actual sale or purchase price and actual bid and offer quotations, the compensation to be received by the broker-dealer and certain associated persons, and must deliver certain disclosures required by the Commission. Consequently, the penny stock rules may make it difficult for you to resell any shares you may purchase.

We are selling the shares of this offering without an underwriter and may be unable to sell any shares.

This offering is self-underwritten, that is, we are not going to engage the services of an underwriter to sell the shares; we intend to sell our shares through our President, Chief Executive Officer and Director Sylvester L. Crawford, who will receive no commissions. There is no guarantee that he will be able to sell any of the shares. Unless he is successful in selling all of the shares of our Company’s offering, we may have to seek alternative financing to implement our business plan.

Due to the lack of a trading market for our securities, you may have difficulty selling any shares you purchase in this offering.

We are not registered on any market or public stock exchange. There is presently no demand for our common stock and no public market exists for the shares being offered in this prospectus. We plan to contact a market maker immediately following the completion of the offering and apply to have the shares quoted on the OTCQB. The OTCQB is a regulated quotation service that display real-time quotes, last sale prices and volume information in over-the-counter securities. The OTCQB is not an issuer listing service, market or exchange. Although the OTCQB does not have any listing requirements per se, to be eligible for quotation on the OTCQB, issuers must remain current in their filings with the SEC or applicable regulatory authority. If we are not able to pay the expenses associated with our reporting obligations we will not be able to apply for quotation on the OTCQB. Market makers are not permitted to begin quotation of a security whose issuer does not meet this filing requirement. Securities already quoted on the OTCQB that become delinquent in their required filings will be removed following a 30 to 60 day grace period if they do not make their required filing during that time. We cannot guarantee that our application will be accepted or approved and our stock listed and quoted for sale. As of the date of this filing, there have been no discussions or understandings between the Company and anyone acting on our behalf, with any market maker regarding participation in a future trading market for our securities. If no market is ever developed for our common stock, it will be difficult for you to sell any shares you purchase in this offering. In such a case, you may find that you are unable to achieve any benefit from your investment or liquidate your shares without considerable delay, if at all. In addition, if we fail to have our common stock quoted on a public trading market, your common stock will not have a quantifiable value and it may be difficult, if not impossible, to ever resell your shares, resulting in an inability to realize any value from your investment.