Prospectus Supplement
(To Prospectus Dated April 7, 2020)

Filed pursuant to Rule 424(b)(5)
Registration No. 333-234449

1,207,744 Shares

AKERS BIOSCIENCES, INC.

Common Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 1,207,744 shares of common stock, no par value per share, to certain institutional and accredited investors at an offering price of $5.67 per share.

Our common stock is currently listed on the Nasdaq Capital Market ("NASDAQ") under the symbol "AKER". On August 10, 2020, the last reported sale price for our common stock on NASDAQ was $6.54 per share.

Investing in our securities involves a high degree of risk. You should purchase our securities only if you can afford a complete loss of your investment. See "Risk Factors" beginning on page S-15 of this prospectus supplement and "Risk Factors" beginning on page 6 of the accompanying prospectus.

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

	Per Share	Total
Offering Price	$ 5.67000	$ 6,847,908.48
Placement agent fees (1)	$ 0.42525	$ 513,593.14
Proceeds, before expenses, to us (2)	$ 5.24475	$ 6,334,315.34

(1) In addition, we have agreed to reimburse the placement agent for certain offering-related expenses, pay a management fee of 1.0% of the gross proceeds raised in this offering and to issue the placement agent or its designees warrants to purchase a number of shares of common stock equal to 8.0% of the shares of common stock sold in this offering. See "Plan of Distribution" beginning on page S-40 for more information regarding the placement agent's compensation.
(2) The amount of the offering proceeds to us presented in this table does not give effect to the sale or exercise, if any, of the warrants being issued to the placement agent.

We have retained H.C. Wainwright & Co., LLC ("Wainwright" or the "placement agent") to act as our exclusive placement agent in connection with this offering. The placement agent is not purchasing the shares of common stock offered by us in this offering and is not required to sell any specific number or dollar amount of securities, but will assist us in this offering on a reasonable best efforts basis.

As of August 11, 2020 immediately before the sale of the shares of common stock offering in this offering, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $48,818,889 based on 7,466,539 shares of outstanding common stock, of which 7,464,662 shares are held by non-affiliates, and a per share price of $6.54 which was the closing sale price of our common stock as reported by NASDAQ on August 10, 2020. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell the securities covered hereby in a public primary offering with a value exceeding more than one-third of the aggregate public market value of our common stock in any 12-month period so long as the aggregate market value of our outstanding common stock held by non-affiliates remains below $75 million. Following the sale of shares in this offering, we will have sold securities with an aggregate market value of $16,272,912.16 pursuant to General Instruction I.B.6 of Form S-3 during the 12-month calendar period that ends on and includes the date hereof.

Delivery of the shares of common stock offered hereby is expected to take place on or about August 13, 2020, subject to satisfaction of certain customary closing conditions.

H.C. Wainwright & Co.

The date of this prospectus supplement is August 11, 2020

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the U.S. Securities and Exchange Commission (the "SEC") utilizing a "shelf" registration process. This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus —the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein. We have not authorized, and the placement agent has not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein or therein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled "Where you can find more information; Information incorporated by reference" in this prospectus supplement and in the accompanying prospectus, respectively.

We are offering to sell, and seeking offers to buy, the securities offered by this prospectus supplement only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the securities offered by this prospectus supplement in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless we have indicated otherwise, or the context otherwise requires, references in this prospectus supplement and the accompanying prospectus to "AKERs" the "Company," "we," "us" and "our" or similar terms refer to Akers Biosciences, Inc., a New Jersey corporation, and its consolidated subsidiaries.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference herein and therein. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including "Risk Factors," the financial statements, and related notes, and the other information incorporated by reference herein and therein.

Our Company

We were historically a developer of rapid health information technologies but since March 2020, have been primarily focused on the development of a vaccine candidate against SARS-CoV-2, a coronavirus currently causing a pandemic throughout the world. In response to the global pandemic, we are pursuing rapid development and manufacturing of our coronavirus vaccine candidate, in collaboration with Premas Biotech PVT Ltd. ("Premas"). With Premas, we are currently conducting animal studies for our SARS-CoV-2 vaccine candidate in India with different dose amounts, including amounts that would be applicable to humans. We and Premas are currently engaged in communications with the U.S. Food and Drug Administration ("FDA") and the office of the drug controller in India.

Coronavirus and COVID-19 Pandemic

In December 2019, SARS-CoV-2 was reported to have surfaced in Wuhan, China, and on March 12, 2020, the World Health Organization ("WHO") declared the global outbreak of COVID-19, the disease caused by SARS-CoV-2, to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, China, and India, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. According to the WHO situation report, dated as of August 6, 2020, approximately 18 million cases were reported globally and 700,000 of these were deadly, making the development of effective vaccines to prevent this disease a major global priority. Although multiple vaccine candidates against SARS-CoV-2 are under development, there is currently no known or approved vaccine or specific antiviral treatment, with the primary treatment being symptomatic and supportive therapies.

Competition

We face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions pursing research and development of technologies, drugs or other therapies that would compete with our products or product candidates. The pharmaceutical market is highly competitive, subject to rapid technological change and significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Our competitors may develop products more rapidly or more effectively than us. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects.

Specifically, the competitive landscape of potential COVID-19 vaccines and treatment therapies has been rapidly developing since the beginning of the COVID-19 pandemic, with several hundreds of companies claiming to be investigating possible candidates and approximately 3,000 studies registered worldwide as investigating COVID-19 (source: clinicaltrials.gov). Given the global footprint and the widespread media attention on the COVID-19 pandemic, there are efforts by public and private entities to develop a COVID-19 vaccine as soon as possible, including large, multinational pharmaceutical companies such as AstraZeneca, GlaxoSmithKline, Johnson & Johnson, Moderna, Pfizer, and Sanofi, with vaccine candidates that are currently at more advanced stage of development than our vaccine candidate. Those other entities may develop COVID-19 vaccines that are more effective than any vaccine we may develop, may develop a COVID-19 vaccine that becomes the standard of care, may develop a COVID-19 vaccine at a lower cost or earlier than we are able to jointly develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 vaccine. Many of these other organizations are much larger than we are and have access to larger pools of capital, and as such, able to fund and carry on larger research and development initiatives. Such other entities may have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of vaccine candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. Our competitors may also have greater name recognition and better access to customers.. In addition, based on the competitive landscape, multiple COVID-19 vaccines or therapeutics may be approved to be marketed. Should another party be successful in producing a more efficacious vaccine for COVID-19, such success could reduce the commercial opportunity for our COVID-19 vaccine candidate and could have a material adverse effect on our business, financial condition, results of operations and future prospects. Moreover, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products that we believe we currently possess. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our vaccine development efforts or for us to ultimately commercialize and market any vaccine candidate, if approved. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

Coronavirus Vaccine Development

On March 23, 2020, we entered into that certain membership interest purchase agreement (as subsequently amended, the "MIPA") with the members (the "Sellers") of Cystron Biotech, LLC ("Cystron"), pursuant to which we acquired 100% of the membership interests (the "Membership Interests") of Cystron. Cystron is a party to a license agreement with Premas whereby Premas granted Cystron, among other things, an exclusive license with respect to Premas' genetically engineered yeast (S. cerevisiae)-based vaccine platform, D-Crypt™, for the development of a vaccine against COVID-19 and other coronavirus infections. We have partnered with Premas on this initiative as we seek to advance this vaccine candidate through the regulatory process, both with the FDA and the office of the drug controller in India. Premas is primarily responsible for the development of the vaccine candidate through proof of concept and is entitled to receive milestone payments upon achievement of certain development milestones through proof of concept.

Premas' D-Crypt platform has been developed to express proteins that are difficult to clone, express and manufacture and are a key component in vaccine development. Premas has identified three major structural proteins of SARS-CoV-2 as antigens for potential vaccine candidates for COVID-19: spike protein or S protein, envelope protein or E protein, and membrane protein or M protein. In April 2020, Premas used its D-Crypt platform to recombinantly express all three of such antigens, which we considered as a significant milestone for development of a triple antigen vaccine. We believe including a combination of all three antigens will provide advantages against the likelihood of protein mutation, in which case a single-protein vaccine can be rendered non-efficacious, and therefore, enhance efficacy of our vaccine candidates. We believe the D-Crypt provides us advantages in vaccine production and manufacturing, as the technology platform is highly scalable with a robust process, which we expect will ultimately result in significant cost savings compared to other similar vaccine platforms. Based on genetically engineered baker's yeast S. cerevisiae, the platform is highly scalable into commercial production quantities and has been previously utilized for the production of multiple human and animal health vaccines candidates during its 10-year development track record. Yeast has a large endoplasmic reticulum, or ER, which is a desirable attribute for expressing membrane protein. In complex cells, ER is where the protein is formed. The larger the surface, the more membrane protein that can attach to the ER inside the cell. Yeast is also generally believed to be easily manipulated and allow for results to be gathered quickly. Yeast multiplies faster than mammalian cells and is cheaper to work with than mammalian systems, which are much more complex and slower to grow comparatively. Because yeast has Generally Recommended as Safe status from the FDA, we believe the D-Crypt platform will be viewed favorably by the FDA and the office of the drug controller in India.

As of May 14, 2020, Premas has successfully completed its vaccine prototype and obtained transmission electron microscopic (TEM) images of the recombinant virus like particle (VLP) assembled in yeast. A manufacturing protocol has also been established and large-scale production studies have been initiated for our vaccine candidate. Though the prototype is complete, the vaccine candidate is still in early stages of development, and, accordingly, must undergo preclinical testing and all phases of clinical trials before we can submit a marketing application (in this case, a biologics license application, or "BLA") to the FDA. The BLA must be approved by the FDA before any biological product, including vaccines, may be lawfully marketed in the United States. We believe the most pivotal, yet difficult, stage in our anticipated development of the contemplated vaccine candidate is the requisite conduct of extensive clinical trials to demonstrate the safety and efficacy of our vaccine candidate. Additionally, after we complete the necessary preclinical testing, but before we may begin any clinical studies in the United States, we must submit an Investigational New Drug ("IND") application to the FDA, as this is required before any clinical studies may be conducted in the United States. In some cases, clinical studies may be conducted in other countries; however, the FDA may not accept data from foreign clinical studies in connection with a BLA (or other marketing application) submission.

In July 2020, animal studies for our vaccine candidate were initiated in India. In addition, we announced that Premas has successfully completed the manufacturing process for the VLP vaccine candidate. Clinical testing is expensive, time consuming, and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed in a timely manner, or at all. Failures in connection with one or more clinical trials can occur at any stage of testing.

Premas owns, and has exclusively licensed rights to us, two provisional Indian patent applications filed in January and March 2020. The scope of these Indian provisional patent applications are directed, respectively, to (i) a platform for the expression of difficult to express proteins (DTE-Ps), which might provide coverage for a method of making the to-be-developed vaccine; and (ii) an expression platform for SARS-CoV-2-like virus proteins, methods relevant thereto, and a relevant vaccine. If non-provisional patent rights are pursued claiming priority to each of these two provisional applications, any resulting patent rights that issue might not expire until approximately January 20, 2041 and March 4, 2041, if all annuities and maintenance fees are timely paid. The expiration dates may be extendable beyond these dates depending on the jurisdiction and the vaccine development process. As we do not own the patents or patent applications that we license, we may need to rely upon Premas to properly prosecute and maintain those patent applications and prevent infringement of those patents.

Impact of the COVID-19 Pandemic on Our Business

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to future developments. These include but are not limited to the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that regulators, or the board or management of the Company, may determine are needed. We do not yet know the full extent of potential delays or impacts on our business, our vaccine development efforts, healthcare systems or the global economy as a whole. However, the effects are likely to have a material impact on our operations, liquidity and capital resources, and we will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, we have implemented work-from-home policies for many of our employees and temporarily modified our operations to comply with applicable social distancing recommendations. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business, including Premas, whose operations are located in India. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we and Premas may engage in connection with the development and testing of our vaccine candidate.

In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Government Regulation and Product Approval

Federal, state, and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our prospective vaccine candidate(s) must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act, and their respective implementing regulations. Products are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to FDA's good laboratory practices (the "GLPs"), and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCP, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with current Good Manufacturing Process ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

Before testing any biological vaccine candidate in humans, the vaccine candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the vaccine candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects having the specific disease.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as "off-label" use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our prospective vaccine candidate(s).

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA, as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the HITECH Act, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Additionally, the Federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

U.S. Healthcare Reform

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our prospective vaccine candidate(s). In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

Recent Developments

Discontinuation of Screening and Testing Products

As previously disclosed, in light of the unfavorable factors persistent in our rapid, point-of-care screening and testing product business and the progress we have made in our partnership with Premas, we conducted a strategic review of the screening and testing products business. Following such review, in early July 2020, we ceased the production and sale of our rapid, point-of-care screening and testing products. We will continue to provide support for these testing products that remain in the market through their respective product expiration dates. We had been experiencing declining sales revenue and production backlogs for these products and, as we previously reported, had eliminated our sales force for such products. We intend to devote our attention to our partnership with Premas for the development of our vaccine candidate for COVID-19 and will continue to explore strategic alternatives that we believe will increase shareholder value. In connection with the discontinuation of our existing product line, on July 16, 2020, we decided to close our facility in West Deptford, New Jersey (the "Thorofare Facility") and exercised the early termination option under the lease agreement, which provided for a 150-day notice to terminate the lease. Pursuant to the early termination option, the lease for the Thorofare Facility will mature on December 13, 2020.

Exploration of Strategic Alternatives

In addition, our board of directors (the "Board") continues to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations. We do not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

ChubeWorkx Settlement Agreement and General Release

On August 3, 2020, we entered into a Settlement Agreement and General Release (the "SAGR") with ChubeWorkx Guernsey Limited ("ChubeWorkx"). We and ChubeWorkx entered into the SAGR to terminate a prior Settlement Agreement, dated August 17, 2016, by and among us and ChubeWorkx (the "Prior Settlement Agreement" and, collectively with all other contracts, agreements and understandings by and between us and ChubeWorkx, whether written or oral, the "Prior Agreements"), pursuant to which we granted ChubeWorkx a security interest in substantially all of our assets, and to fully and finally settle and compromise any and all current and future claims and liabilities of any nature arising between us and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements, on the terms set forth in the SAGR.

As consideration for the settlement of claims pursuant to the SAGR, we agreed to (i) pay to ChubeWorkx an amount equal to $300,000 and (ii) deliver to ChubeWorkx with 500,000 shares of our common stock. We granted ChubeWorkx registration rights with respect to such shares. In the event that the we fail to file a resale registration statement covering the such shares by August 18, 2020 (the "Filing Deadline"), or fails to cause such registration statement to be declared effective by the earlier of October 2, 2020 or 45 days after the filing of such registration statement (the "Effectiveness Deadline"), then, on each of the Filing Deadline and the Effectiveness Deadline, as the case may be, and on each monthly anniversary thereof (if the such registration statement shall not have been filed or declared effective by such date, as the case may be) until such registration statement is filed or declared effective, we shall pay to ChubeWorkx an amount in cash, as partial liquidated damages equal to 1.0% of the market value of 500,000 shares of our common stock issued to ChubeWorkx pursuant to the SAGR.

As of the earlier to occur, following and subject to delivery and complete full effective legal transfer to ChubeWorkx of the shares of our common stock and delivery of the cash payment to ChubeWorkx in full in accordance with the provisions of the SAGR, of (i) the date that the resale registration statement covering the such shares is declared effective by the SEC and (ii) the date that all of such shares may be resold by ChubeWorkx under Rule 144 of the Securities Act of 1933, as amended, without restriction (the "Release Date"), any and all claims, differences, and disputes of any current and/or future claims and/or liabilities arising between us and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements shall be deemed fully and finally settled and compromised (with the exception of any claims arising under the SAGR or the Leak-Out and Support Agreement described below). As of the Release Date, each of the Prior Agreements will be terminated, and ChubeWorkx will automatically and irrevocably release all security interests and liens created under the Security Agreement or otherwise as security for our obligations under the Prior Agreements.

Chubeworkx Leak-Out and Support Agreement

On August 3, 2020, as an inducement to enter into the SAGR, and as one of the conditions to the consummation of the transactions contemplated by the SAGR, ChubeWorkx entered into a Leak-Out and Support Agreement with us, pursuant to which ChubeWorkx agreed to vote its shares of common stock issued pursuant to the SAGR in favor of each matter proposed and recommended for approval by the Board or management at every meeting of the stockholders and on any action or approval by written consent of the stockholders.

Corporate Governance Reforms

On May 28, 2020, the United Stated District Court for the District of New Jersey approved that certain Amended Stipulation and Agreement of Settlement, dated October 1, 2019 (the "Settlement") among the settling parties in connection with a consolidated shareholder derivative action, Case No.: 2:18-cv-15992. Pursuant to the Settlement, effective as of July 21, 2020, we made various modifications to our corporate governance and business ethics practices as further discussed below.

On July 21, 2020, our Board adopted amended and restated bylaws (the "A&R Bylaws") that became effective as of July 21, 2020 pursuant to the Settlement. The A&R Bylaws were adopted to require that, among other things: (i) each member of the Board attend each annual meeting of our shareholders in person, absent extraordinary circumstances; (ii) the role of the Chairman of the Board be rotated among our independent directors every five years; (iii) at least half (50%) of the Board be comprised of directors who qualify as independent directors under applicable listing standards of The Nasdaq Stock Market LLC; (iv) our independent directors to meet in executive session following each Board meeting, in no event less than four (4) times per year; (v) following November 27, 2020, the positions of Chairman of the Board and Chief Executive Officer are to be held by different individuals, and (vi) following November 27, 2020, no one person shall serve the positions of the chief executive officer and the chief financial officer. Pursuant to the Settlement, these changes will remain in place for at least four years.

In addition, pursuant to the Settlement, on July 21, 2020, the Board formed a risk and disclosure committee (the "Risk and Disclosure Committee") and adopted a new whistleblower policy (the "Whistleblower Policy") and a charter for the Risk and Disclosure Committee (the "Risk and Disclosure Committee Charter") to govern the Risk and Disclosure Committee. In order to align our Code of Ethics (the "Code") that applies to all of our directors, officers, and employees with the newly adopted Whistleblower Policy and the Risk and Disclosure Committee Charter, the Board revised the Code. As required by the Settlement, any waivers of any provision of the Code may be granted only by the Risk and Disclosure Committee. In addition, the Code was revised to clarify the enforcement mechanism for violations of the Code. Furthermore, pursuant to the Settlement, the Board approved and adopted revised charters of our standing committees.

Departure of Interim Chief Financial Officer

On July 19, 2020, we and Howard R. Yeaton, our Interim Chief Financial Officer, agreed by mutual understanding that Mr. Yeaton's employment as our officer and employee will cease effective August 19, 2020, in accordance with the terms of his employment agreement dated January 6, 2020.

Appointment of Chief Financial Officer

On July 21, 2020, we entered into a CFO Consulting Agreement (the "Consulting Agreement") with Brio Financial Group ("Brio"), pursuant to which we appointed Mr. Stuart Benson as Chief Financial Officer, effective August 19, 2020, with a term ending June 30, 2021. Pursuant to the Consulting Agreement, we will pay Brio an initial retainer fee of $7,500 and a fixed monthly payment of $13,500, commencing August 15, 2020. We will also be billed for travel and other out-of-pocket costs, such as report production, postage, etc.

MIPA

On March 23, 2020, we acquired Cystron pursuant to the MIPA. Approximately one-third of Cystron was owned by two entities, each of which is controlled by an associated person of the placement agent (collectively, the "Associated Persons"). The Associated Persons will accrue approximately one-third of the consideration and are entitled to the same percentage of any future consideration under the MIPA.

As consideration for the Membership Interests purchased from the Associated Persons, we have delivered to the Associated Persons, collectively: (x) 142,259 shares of our common stock and 65,369 shares of our preferred stock, and (y) approximately $333,333.

Additionally, we are required to (A) make an initial payment to the Sellers of up to $1,000,000 upon our receipt of cumulative gross proceeds from the consummation of an initial equity offering after the date of the MIPA of $8,000,000, and (B) pay to Sellers an amount in cash equal to 10% of the gross proceeds in excess of $8,000,000 raised from future equity offerings after the date of the MIPA until the Sellers have received an aggregate additional cash consideration equal to $10,000,000 (collectively, the "Equity Offering Payments"). On May 14, 2020, we and the Sellers entered into an Amendment No. 1 to the MIPA (the "Amendment"), which provided that any Equity Offering Payments in respect of an equity offering that is consummated prior to September 23, 2020, shall be accrued, but shall not be due and payable until September 24, 2020. The other provisions of the MIPA remain unmodified and in full force and effect. Upon the achievement of certain milestones, including the completion of a Phase 2 study for a COVID-19 vaccine that meets its primary endpoints, Sellers will be entitled to receive an additional 750,000 shares of our common stock or, in the event we are unable to obtain stockholder approval for the issuance of such shares, 750,000 shares of non-voting preferred stock that are valued following the achievement of such milestones and shall bear a 10% annual dividend (the "Milestone Shares"). Sellers will also be entitled to contingent payments from us of up to $20,750,000 upon the achievement of certain milestones, including the approval of a new drug application by the FDA.

Pursuant to the MIPA, upon our consummation of the registered direct equity offering closed on April 8, 2020 (the "April Offering"), we paid the Sellers $250,000 on April 20, 2020 (including approximately $83,333 paid to the Associated Persons). On April 30, 2020, Premas, one of the Sellers, returned to us $83,334, representing their portion of the $250,000 amount paid to the Sellers on April 20, 2020. Premas has advised us that these funds were returned temporarily in order for Premas to meet certain regulatory requirements in India. The closing of another registered direct equity offering on May 18, 2020 (the "May Offering"), triggered an accrued payment to the Sellers of approximately $892,500, which, pursuant to the Amendment, will be due and payable on September 24, 2020 (including approximately $297,500 to be accrued by the Associated Persons).

The closing of this offering will trigger an accrued payment to the Seller of approximately $684,790.85 (equal to 10% of the gross proceeds raised from this offering), which will be due and payable on September 24, 2020 (including approximately $228,263.62 to be accrued by the Associated Persons).

We shall also make quarterly royalty payments to Sellers equal to 5% of the net sales of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine") for a period of five (5) years following the first commercial sale of the COVID-19 Vaccine, provided that such payment shall be reduced to 3% for any net sales of the COVID-19 Vaccine above $500 million.

In addition, Sellers shall be entitled to receive 12.5% of the transaction value, as defined in the MIPA, of any change of control transaction, as defined in the MIPA, that occurs prior to the fifth (5th) anniversary of the closing date of the MIPA, provided that we are still developing the COVID-19 Vaccine at that time. Following the consummation of any change of control transaction, the Sellers shall not be entitled to any payments as described above under the MIPA.

April Offering

In connection with the April Offering, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated April 7, 2020, we issued and sold an aggregate of 766,667 shares of our common stock at an offering price of $6.00 per share, for gross and net proceeds of approximately $4.6 million and $4.1 million, respectively, which closed on April 8, 2020.

May Offering

In connection with the May Offering, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated May 14, 2020, we issued and sold an aggregate of 1,366,856 shares of our common stock at an offering price of $3.53 per share, for gross and net proceeds of approximately $4.8 million and $4.3 million, respectively, which closed on May 14, 2020.

Corporate Information

We were incorporated in 1989 in the state of New Jersey. Our principal executive offices are located at 201 Grove Road, Thorofare, New Jersey USA 08086. Our telephone number is (856) 848-8698. Our corporate website address is www.AkersBio.com. The information contained on or accessible through our website is not a part of this prospectus supplement and is not incorporated in this prospectus supplement, unless otherwise stated, and the inclusion of our website address in this prospectus is an inactive textual reference only.

THE OFFERING

Common stock offered by us pursuant to this prospectus supplement	1,207,744 shares
Common stock to be outstanding immediately after this offering (1)	8,674,283 shares (assuming that we sell the maximum number of shares of common stock offered in this offering and excluding shares issuable upon the exercise of the warrants to be issued to the placement agent).
Offering price per share	$5.67 per share
Use of proceeds	We expect to receive net proceeds from this offering of approximately $6.2 million after deducting the placement agent fees and the estimated offering expenses payable by us. We intend to use the net proceeds from this offering for general working capital and for corporate purposes. See "Use of Proceeds" on page S-37 of this prospectus supplement.
Dividend policy	We have never paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future but intend to retain our capital resources for reinvestment in our business. See "Dividend Policy."
Risk factors	Investing in our securities involves a high degree of risk. You should read the "Risk Factors" section on page S-15 of this prospectus supplement and page 6 of the accompanying prospectus and in the documents incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to invest in our securities.
NASDAQ symbol	AKER

(1) The number of shares of common stock to be outstanding immediately after this offering is based on 7,466,539 shares of our common stock outstanding as of August 11, 2020, and excludes, as of such date:

- 417,896 shares of common stock issuable upon the exercise of common stock warrants outstanding at a weighted average exercise price of $20.88 per share;
- 40 shares of common stock issuable upon the exercise of options outstanding at a weighted average exercise price of $236.16 per share;
- 15,603 shares of common stock issuable upon the vesting of restricted stock units;
- 67,959 shares of common stock available for future issuance under our equity compensation plans;
- 208,577 shares of common stock issuable upon the conversion of the Series D Convertible Preferred Stock;
- 105,000 shares of common stock issuable upon the conversion of 105,000 shares of our Series C Convertible Preferred Stock issuable upon the exercise of warrants at an exercise price of $4.00 per share; and
- 96,620 shares of common stock issuable upon exercise of the placement agent warrants with an exercise price of $7.0875 to be issued to the placement agent as compensation in connection in this offering.

Unless otherwise indicated, all information contained in this prospectus supplement assumes no exercise of the placement agent warrants to be issued to the placement agent in connection with this offering.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you make a decision to invest in our securities, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein. You should also consider the risks, uncertainties and assumptions discussed in other reports that we file with the SEC which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also significantly impair our business operations and could result in a complete loss of your investment. Please also read carefully the section entitled "Cautionary Note Regarding Forward-Looking Statements" in this prospectus supplement.

RISKS RELATED TO OUR ACQUISITION

We may fail to realize the anticipated benefits of our acquisition of Cystron and those benefits may take longer to realize than expected.

On March 23, 2020, we entered into the MIPA with the Sellers, pursuant to which we will acquire the Membership Interests of Cystron. Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas. As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of the COVID-19 Vaccine Candidate. Our ability to realize the anticipated benefits of the acquisition will depend, to a large extent, on our ability to produce an effective vaccine against COVID-19. The development of the COVID-19 Vaccine Candidate is in very early stages and there is no assurance that we will be able to produce an effective vaccine. The failure to produce the COVID-19 Vaccine Candidate could adversely affect our business, financial condition and results of operations. In addition, we expect to incur significant expenses related to the acquisition. These expenses include, but are not limited to, the Common Stock Consideration, a cash consideration of $1.0 million, related contingent fees, legal fees and other related fees and expenses. Many of these expenses will be payable by us regardless of our ability to successfully develop the COVID-19 Vaccine Candidate, and we will not be able to recover these expenses in the event that we fail to develop the COVID-19 Vaccine Candidate.

Our acquisition of Cystron could result in additional costs, integration or operating difficulties, dilution and other adverse consequences.

In connection with the acquisition of the Cystron and in pursuit of developing the COVID-19 Vaccine Candidate, we may:

- issue equity securities that may substantially dilute our stockholders' percentage of ownership;
- be obligated to make milestone, royalty or other contingent or non-contingent payments; and
- incur debt or non-recurring and other charges, or assume liabilities.

In addition, the process of integrating Cystron's business may create operating difficulties and expenditures and pose numerous additional risks to our operations, including:

- failure to develop, manufacture or supply the COVID-19 Vaccine Candidate economically or successfully commercialize or achieve market acceptance of the COVID-19 Vaccine Candidate;
- exposure to liabilities of Cystron, including known or unknown risks relating to the validity or enforceability of exclusivity rights and generic competition;

- adverse effects on our operating results or financial condition, including due to expenditures or acquisition-related costs, costs of commercialization or amortization or impairment costs for acquired goodwill and other intangible assets;
- impairment of relationships with key suppliers and manufacturers due to changes in management and ownership and difficulty in maintaining existing agreements, licenses and other arrangements or rights on substantially similar terms as existed prior to the acquisition;
- regulatory changes and market dynamics after the acquisition; and
- potential loss of key employees, particularly those of the acquired entity.

If any of the above events (or more) occur, or if we cannot effectively manage or respond to such events following the acquisition, they may have material adverse effect on our business, results of operations and financial condition.

Cystron is dependent on technologies that it has licensed, and Cystron may need to license in the future, and if Cystron fails to obtain licenses it needs, or fails to comply with its payment obligations in the agreements under which Cystron in-license intellectual property and other rights from third parties, Cystron could lose its ability to develop a COVID-19.

Cystron currently is dependent on a license from Premas for its key technologies. Any failure to make the payments required by the License Agreement may permit Premas to terminate the license. If Cystron were to lose or otherwise be unable to maintain the license for any reason, it would halt Cystron's ability to develop a COVID-19 Vaccine Candidate. The foregoing could result in a material adverse effect on our business or results of operations.

In addition, Cystron does not own the patents or patent applications that it licenses, and as such, Cystron may need to rely upon Premas to properly prosecute and maintain those patent applications and prevent infringement of those patents. If Premas is unable to adequately protect their proprietary intellectual property Cystron licenses from legal challenges, or Cystron is unable to enforce such licensed intellectual property against infringement or alternative technologies, we will not be able to compete effectively in the drug discovery and development business.

RISKS RELATED TO OUR BUSINESS

We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability.

We have recorded a net loss attributable to common stockholders in most reporting periods since our inception. Our net losses for the years ended December 31, 2019 and 2018 were $3,888,249 and $10,849,034, respectively. We had a net loss of $7,166,667 million during the six months ended June 30, 2020. Our accumulated deficit at June 30, 2020 was $126,749,797. On account of the unfavorable factors existing within our rapid, point-of-care screening and testing products business, we ceased the production and sale of our screening testing products. We intend to focus on the development of the COVID-19 Vaccine Candidate in partnership with Premas and expect to incur additional operating losses for the foreseeable future. We also plan to continue to explore strategic alternatives that we believe will increase shareholder value. However, there can be no assurance of success in reducing our loss, becoming profitable, or having sufficient cash to develop a COVID-19 Vaccine Candidate or to complete a strategic alternative transaction.

Our pursuit of the COVID-19 Vaccine Candidate is at an early stage. We have not previously tested our rapid response capability and may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all.

In response to the COVID-19 pandemic, we are pursuing the rapid development of the COVID-19 Vaccine. Our development of the vaccine is in early stages, and we may be unable to produce a vaccine candidate against SARS-CoV-2, a coronavirus causing the COVID-19 pandemic in a timely manner, if at all. Additionally, our ability to develop an effective vaccine depends on the success of our rapid response capability, which we have not previously tested and which will need to be funded by third parties in order to enable us to have sufficient capacity to respond to a global health challenge. If the pandemic is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture the COVID-19 Vaccine, we may be unable to successfully generate revenue from the manufacturing of the COVID-19 Vaccine. We are also committing financial resources and personnel to the development of the COVID-19 Vaccine Candidate which may divert resources from other strategic alternative transactions, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

We operate in a highly competitive industry.

We face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions pursing research and development of technologies, drugs or other therapies that would compete with our products or product candidates. The pharmaceutical market is highly competitive, subject to rapid technological change and significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Our competitors may develop products more rapidly or more effectively than us. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects and may also lead to the diversion of funding away from us and toward other companies.

Specifically, the competitive landscape of potential COVID-19 vaccines and treatment therapies has been rapidly developing since the beginning of the COVID-19 pandemic, with several hundreds of companies claiming to be investigating possible candidates and approximately 3,000 studies registered worldwide as investigating COVID-19 *(source: clinicaltrials.gov)*. Given the global footprint and the widespread media attention on the COVID-19 pandemic, there are efforts by public and private entities to develop a COVID-19 Vaccine Candidate as soon as possible, including large, multinational pharmaceutical companies such as AstraZeneca, GlaxoSmithKline, Johnson & Johnson, Moderna, Pfizer, and Sanofi, with vaccine candidates that are currently at more advanced stage of development than our vaccine candidate. Those other entities may develop COVID-19 vaccines that are more effective than any vaccine we may develop, may develop a COVID-19 Vaccine Candidate that becomes the standard of care, may develop a COVID-19 Vaccine Candidate at a lower cost or earlier than we are able to jointly develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 Vaccine. Many of these other organizations are much larger than we are and have access to larger pools of capital, and as such, able to fund and carry on larger research and development initiatives. Such other entities may have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of vaccine candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. Our competitors may also have greater name recognition and better access to customer. In addition, based on the competitive landscape, multiple COVID-19 vaccines or therapeutics may be approved to be marketed. Should another party be successful in producing a more efficacious vaccine for COVID-19, such success could reduce the commercial opportunity for our COVID-19 Vaccine Candidate and could have a material adverse effect on our business, financial condition, results of operations and future prospects. Moreover, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products that we believe we currently possess. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our vaccine development efforts or for us to ultimately commercialize and market any vaccine candidate, if approved. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

Our business may be materially adversely affected by the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures, including in the United States and India. On March 12, 2020, the WHO declared COVID-19 to be a global pandemic. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases.

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our vaccine development efforts, healthcare systems or the global economy as a whole. However, the effects are likely to have a material impact on our operations, liquidity and capital resources, and we will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, we have implemented work-from-home policies for many of our employees and temporarily modified our operations to comply with applicable social distancing recommendations. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business, including Premas, whose operations are located in India. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we and Premas may engage in connection with the development and testing of our vaccine candidate.

The anticipated economic consequences of the COVID-19 pandemic have adversely impacted financial markets, resulting in high share price volatility, reduced market liquidity, and substantial declines in the market prices of the shares of most publicly traded companies, including Akers. Volatile or declining markets for equities could adversely affect our ability to raise capital when needed through the sale of shares of common stock or other equity securities. Should these market conditions persist when we need to raise capital, and if we are able to sell shares of our common stock under then prevailing market conditions, we might have to accept lower prices for our shares and issue a larger number of shares than might have been the case under better market conditions, resulting in significant dilution of the interests of our shareholders.

With regard to our contemplated coronavirus vaccine candidate, we must conduct preclinical testing, prepare and submit an IND to the FDA, and conduct all phases of clinical studies (which may include postmarket or "Phase 4" studies), which will likely take several years and substantial expenses to complete, before we can submit an application for marketing approval to the FDA, and there is no guarantee that we will complete such clinical development in a timely manner or at all or that our BLA will be approved, if submitted.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our contemplated vaccine candidate for coronavirus. Accordingly, our business currently depends heavily on the successful development, FDA approval, and commercialization of such candidate, which may never receive FDA approval or be successfully commercialized even if FDA approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of our contemplated vaccine candidate are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, as applicable. We are not permitted to market our tablet vaccines in the United States until we receive FDA approval of our applicable BLA. To date, we have not-yet begun any preclinical studies for the COVID-19 Vaccine Candidate, nor have we prepared or submitted an IND. Accordingly, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future, as there are numerous developmental steps that must be completed before we can prepare and submit a BLA.

In the United States, the FDA regulates pharmaceutical and biological products (including vaccines and vaccine candidates, such as the COVID-19 Vaccine Candidate currently in early stages of development) under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act, as well as their respective implementing regulations. Such products and product candidates are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies in accordance with FDA's good laboratory practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials in the United States may begin;

- performance of adequate and well-controlled human clinical trials in accordance with FDA's IND regulations, good clinical practices ("GCPs"), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a BLA for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of preclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with current cGMPs and assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or denial, of the BLA.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Our vaccine candidate is in the earliest stages of clinical development and, therefore, a long way from BLA submission. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for our vaccine candidate or whether any such BLA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also lengthy and requires substantial time and effort. We estimate that the clinical trials we need to conduct to be in a position to submit a BLA for our vaccine candidate for coronavirus will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Also, the results of early preclinical and clinical testing of the COVID-19 Vaccine Candidate may not be predictive of the results of subsequent clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their vaccine candidates performed satisfactorily in preclinical studies and clinical trials have, nonetheless, failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. Any failure or substantial delay in our vaccine development plans may have a material adverse effect on our business.

We may opt to conduct future clinical studies for our contemplated vaccine candidate outside the United States, which could heighten the risk of delay and/or failure, as the FDA may not accept data from such studies in support of any BLA we may submit after completing the applicable developmental and regulatory prerequisites, if ever.

We are still in the earliest stages of development with respect to our contemplated coronavirus vaccine candidate and may ultimately decide to conduct preclinical and/or clinical studies in one or more countries outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States that are not conducted under an IND, the FDA's acceptance of such data is subject to certain conditions. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles and all applicable FDA regulations. The trial population must also adequately represent the intended U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to market the vaccine candidate in the United States, if approved. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its ability to verify the data and its determination that the trials also complied with all applicable U.S. laws and regulations. We cannot guarantee that the FDA will accept data from trials we conduct outside of the United States, if any. If the FDA does not accept the data from such clinical trials, it would likely result in the need for additional trials and the completion of additional regulatory steps, which would be costly and time-consuming and could delay or permanently halt our development of the contemplated candidate.

If we are successful in producing the COVID-19 Vaccine Candidate, we may need to devote significant resources to its scale-up and development including for use by the U.S. government.

In the event that the preclinical and clinical trials for the COVID-19 Vaccine Candidate are perceived to be successful, we may need to work toward the large scale technical development, manufacturing scale-up and larger scale deployment of this potential vaccine through a variety of U.S. government mechanisms such as an Expanded Access Program or an Emergency Use Authorization program. In this case we may need to divert significant resources to this program, which would require diversion of resources from our other businesses. In addition, since the path to licensure of any vaccine against COVID-19 is unclear, if use of the vaccine is mandated by the U.S. government, we may have a widely used vaccine in circulation in the United States or another country prior to our full validation of the overall long term safety and efficacy profile of our vaccine platform and technology. Unexpected safety issues in these circumstances could lead to significant reputational damage for the Company going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

We may be unable to advance the COVID-19 Vaccine Candidate successfully through the preclinical and clinical development process.

Our ability to develop, obtain regulatory approval for, and ultimately commercialize, the COVID-19 Vaccine Candidate effectively will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials;
- successful achievement of the objectives of planned preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing efficient and effective commercial manufacturing, supply and distribution arrangements;
- establishing sufficient market share and promoting acceptance of the product by patients, the medical community and third-party payors;

- successfully executing an effective pricing and reimbursement strategy;
- maintaining a continued acceptable safety and adverse event profile following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims.

The COVID-19 Vaccine Candidate will require additional non-clinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can be in a position to generate any revenue from product sales. We are not permitted to market or promote any vaccine before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. If we are unable to develop or receive marketing approval in a timely manner or at all, we could experience significant delays or an inability to commercialize the COVID-19 Vaccine Candidate, which would materially and adversely affect our business, financial condition and results of operations.

Government involvement may limit the commercial success of our COVID-19 Vaccine Candidate.

The COVID-19 pandemic has been classified as a pandemic by public health authorities, and it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities.

Various government entities, including the U.S. government, are offering incentives, grants, and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share, if any, for our COVID-19 Vaccine Candidate even if we succeed in developing one.

We expect to require additional capital in the future in order to develop our vaccine candidate and to pursue strategic alternative transactions. If we do not obtain any such additional financing, it may be difficult to effectively realize our long-term strategic goals and objectives.

Our current cash resources will not be sufficient to fund the development of our vaccine candidate through all of the required clinical trials to receive regulatory approval and commercialization. While we do not currently have an estimate of all of the costs that it will incur in the development of the COVID-19 Vaccine, we anticipate that it will need to raise significant additional funds in order to continue the development of our vaccine candidate during the next 12-months. In addition, we could also have increased capital needs if it were to engage in a strategic alternative transaction. If we cannot secure this additional funding when such funds are required, we may fail to develop a COVID-19 Vaccine Candidate or be forced to forego certain strategic opportunities.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

If we fail to obtain regulatory approval in foreign jurisdictions, then we cannot market our COVID-19 Vaccine in those jurisdictions.

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to the sale of some medical devices within the European Union. Some of our products that require CE Markings have them. We may be required to conduct additional testing or to provide additional information, resulting in additional expenses, to obtain necessary approvals. If we fail to obtain approval in such foreign jurisdictions, we would not be able to sell our products in such jurisdictions, thereby reducing the potential revenue from the sale of our products.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for a 510(k) clearance of new products;
- withdrawing a 510(k) clearance already granted; and
- criminal prosecution.

Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Even if we are able to commercialize our prospective or future product candidates, the products may not receive coverage or adequate reimbursement from third-party payors in the United States or in other countries in which we seek to commercialize such products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment.

Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

We may not have the resources to conduct clinical protocols sufficient to yield data suitable for publication in peer-reviewed journals and our inability to do so in the future could have an adverse effect on marketing our products effectively.

In order for our products targeted for use by hospital laboratory professionals and healthcare providers to be widely adopted, we would have to conduct clinical protocols that are designed to yield data suitable for publication in peer-reviewed journals. These studies are often time-consuming, labor-intensive and expensive to execute. We have not had the resources to effectively implement such clinical programs within our clinical development activities and may not be able to do so in the future. In addition, if a protocol is initiated, the results of which may ultimately not support the anticipated positioning and benefit proposition for the product. Either of these scenarios could hinder our ability to market our products and revenue may decline.

We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development.

The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold;
- patients do not enroll in a clinical study or results from patients are not received at the expected rate;
- patients discontinue participation in a clinical study prior to the scheduled endpoint at a higher than expected rate;
- patients experience adverse events from a product we develop;
- third-party clinical investigators do not perform the studies in accordance with the anticipated schedule or consistent with the study protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- third-party clinical investigators engage in activities that, even if not directly associated with our studies, result in their debarment, loss of licensure, or other legal or regulatory sanction;
- regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the preclinical or clinical studies;
- changes in governmental regulations or administrative actions;
- the interim results of the preclinical or clinical study, if any, are inconclusive or negative; and
- the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety.

If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future. Preclinical studies and clinical trials are expensive and difficult to design and implement and any delays or prolongment in our preclinical and clinical studies will require additional capital. There is no assurance that we will be able to acquire additional capital to support our studies. The failure to obtain additional capital would have a material adverse effect on the Company.

We anticipate that we will rely completely on third parties to manufacture certain preclinical and all clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. In order to develop products, apply for regulatory approvals and commercialize our products, we will need to develop, contract for, or otherwise arrange for access to the necessary manufacturing capabilities. We anticipate that we will rely on CMOs, or contract manufacturing organizations, and other third party contractors, some of whom may have limited cGMP experience, to manufacture formulations and produce larger scale amounts of drug substance and the drug product required for any clinical trials that we initiate.

The manufacturing process for any vaccine candidate is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. In addition, if we receive the necessary regulatory approval for any product candidate, we also expect to rely on third parties to produce materials required for commercial supply. We may experience difficulty in obtaining adequate manufacturing capacity for our needs. Furthermore, it is our responsibility to ensure that all of our third-party contractors meet cGMP laws, regulations and guidance. Due to their failure to comply with applicable regulatory requirements, we may face fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. These actions could have a material impact on the availability of products. If we are unable to obtain or maintain contract manufacturing for these product candidates, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our products.

To the extent that we enter into manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner and consistent with regulatory requirements, including those related to quality control and quality assurance. The failure of a third-party manufacturer to perform its obligations as expected could adversely affect our business in a number of ways, including:

- we may not be able to initiate or continue preclinical and clinical trials of products that are under development;
- we may need to repeat pivotal clinical trials;
- we may be delayed in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- we may lose the cooperation of our collaborators;
- our products could be the subject of inspections by regulatory authorities;
- we may be required to cease distribution or recall some or all batches of our products; and
- ultimately, we may not be able to meet commercial demands for our products.

If a third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to seek out one or more other third-party manufacturers to manufacture our preclinical and/or clinical trial materials, which could cause delays in the FDA approval process. Further, should our vaccine candidate be approved for marketing by the FDA, a change in a third-party manufacturer could cause significant delays to meeting the demand of patients. In some cases, the technical skills required to manufacture our product may be unique to the original manufacturer and we may have difficulty transferring such skills to a back-up or alternate manufacturer, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also be required to demonstrate that the newly manufactured material is the same or similar to the previously manufactured material, or we may need to repeat clinical trials with the newly manufactured material. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently, which would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our products.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We plan to rely upon third-party contract research organizations, or CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. We expect to continue to rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, current Good Clinical Practices or cGCP, and current Good Laboratory Practices, or cGLP, which are a collection of laws and regulations enforced by the FDA or comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of manufacturing facilities, preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products manufactured consistently with cGMP regulations. Failure by us or our third party CRO to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

If any of our relationships with these third-party CROs, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. 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 preclinical and clinical programs. If CROs do not successfully carry out their contractual duties, or comply with cGCP laws, regulations and guidance, or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We may fail to retain qualified personnel.

We have substantially reduced the number of our employees in order to reduce our costs. Accordingly, retaining our remaining personnel in the future will be critical to our success. If we fail to retain and motivate these highly skilled personnel, we may be unable to continue our operating activities, and this could have a material adverse effect on our business, financial condition, results of operations and future prospects.

We rely on the key executive officer of the management team.

We are dependent on our management team to execute against our business plan. Failure could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

Expenses incurred with respect to monitoring, protecting, and defending our intellectual property rights could adversely affect our business.

Competitors and others may infringe on our intellectual property rights, or may allege that we have infringed on theirs. Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect infringement or misappropriation of our proprietary rights.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

Some or all of our patent applications may not result in the issue of patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated, found unenforceable or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position. Patentability, invalidity, freedom-to-operate or other opinions may be required to determine the scope and validity of third-party proprietary rights. If we choose to go to court to stop a third party from using the inventions protected by our patent, that third party would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court will decide that our patents are not valid or that we cannot stop the other party from using their inventions. There is also the risk that, even if the validity of these patents is upheld, the court will find that the third party's activities do not infringe our rights in these patents.

Furthermore, a third party may claim that we are infringing the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products or product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party's treble damages or attorneys' fees for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the claims of the relevant patent and/or that the third-party patent claims are invalid, and we may not be able to do this. Proving invalidity in the United Sates is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claims.

The use of our PIFA products could result in serious injuries, product liability claims, regulatory enforcement action, and/or recalls or market withdrawals, any of which would likely subject us to substantial costs and reputational harm and have a material adverse effect on our business.

In July 2020, we ceased the production and sale of our rapid, point-of-care screening and testing products. We will continue to provide support for these testing products that remain in the market through their respective product expiration dates. We believe that the users of our PIFA products are likely to be particularly sensitive to test defects and errors, as the conditions that the PIFA products are designed to identify may cause limb- and life-threatening complications if not accurately diagnosed in a timely manner. As a result, the failure of our tests or services to perform as expected could subject us to legal claims arising from any defects or errors.

The use of our PIFA products and our other products could lead to product liability (and other similar) claims against us if someone were to allege that one of our tests failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results, or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with the results generated by our products. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Our PIFA products are not 100% accurate and may generate erroneous results that could cause patient harm. For example, PIFA could provide a so-called "false negative" result upon which a patient or physician may rely to make a conclusion about how to proceed with the patient's treatment. If the false negative causes, or exacerbates, a patient injury or condition, the patient (and/or the patient's family) may file a lawsuit against us based on product liability.

Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated or prevent us from securing insurance coverage in the future.

Further, under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We may be at risk that our former employees may wrongfully use or disclose our trade secrets.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee, former employee, consultant, former consultant or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We are currently subject to a number of securities litigations and we may be subject to similar or other litigation in the future.

We are currently subject to a number of litigations as described in the "Legal Proceedings" section. In connection with certain of these litigations, we have entered into settlements of claims for significant monetary damages. We may also be subject to judgements or enter into additional settlements of claims for significant monetary damages for the securities litigations that we have yet to enter into settlement agreements. Defending against the current litigations is or can be time-consuming, expensive and cause diversion of our management's attention.

With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuit. Substantial litigation costs, including the substantial self-insured retention that we are required to satisfy before any insurance applies to a claim, unreimbursed legal fees or an adverse result in any litigation may adversely impact our business, operating results or financial condition. We believe that our directors' and officers' liability insurance will cover our potential liability with respect to the securities class-action lawsuit; however, the insurer has reserved its rights to contest the applicability of the insurance to such claims and the limits of the insurance may be insufficient to cover our eventual liability.

If we market products or interact with health care practitioners in a manner that violates healthcare fraud or abuse laws, we may be subject to civil or criminal penalties, including exclusion from participation in government healthcare programs.

If we receive payments directly from or bill directly to Medicare, Medicaid or other national or third-party payers for our products, U.S. federal and state healthcare laws and regulations pertaining to fraud or abuse will be applicable to our business. We are subject to healthcare fraud and abuse regulation by the U.S. federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include the federal healthcare program anti-kickback statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, the purchase, lease or order, or arrangement for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates, engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses and submitting inflated best price information to the Medicaid Drug Rebate Program.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. The false statements statute immediately noted above prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians. The ACA, through the Physician Payment Sunshine Act of 2010, imposed new requirements on manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members. Manufacturers are required to report such data to the government by the 90th calendar day of each year.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. Moreover, certain states mandate the tracking and reporting of gifts, compensation and other remuneration paid by us to physicians and other healthcare providers.

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

Our internal computer systems, or those of our third-party vendors, collaborators, or other contractors may be subject to various federal and state confidentiality and privacy laws in the United States and abroad and could sustain system failures, security breaches, or other disruptions, any of which could have a material adverse effect on our business.

Numerous international, national, federal, provincial and state laws, including state privacy laws (such as the California Consumer Privacy Act, or "CCPA"), state security breach notification and information security laws, and federal and state consumer protection laws govern the collection, use, and disclosure of personal information. In addition, most healthcare providers who may, in future, prescribe and dispense our products in the United States and research institutions in the United States with whom we may collaborate in the future are "covered entities" subject to privacy and security requirements under HIPAA. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. We could be subject to a wide range of penalties and sanctions under HIPAA, including criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a covered entity in a manner that is not authorized or permitted by HIPAA. Failure to comply with applicable HIPAA requirements or other current and future privacy laws and regulations could result in governmental enforcement actions (including the imposition of significant penalties), criminal and civil liability, and/or adverse publicity that negatively affects our business.

Moreover, we rely on our internal and third-party provided information technology systems and applications to support our operations and to maintain and process company information including personal information, confidential business information and proprietary information. If these information technology systems are subject to cybersecurity attacks, or are otherwise compromised, due to cyberattacks, human error or malfeasance, system errors or otherwise, it may adversely impact our business, disrupt our operations, or lead to the loss, theft, destruction, corruption, or compromise of our information or that of our collaborators, study subjects, or other third-party contractors, as applicable. Such information technology or security events could also lead to legal liability, regulatory investigations or enforcement actions, loss of business, negative media coverage, and reputational damage. While we seek to protect our information technology systems from these types of incidents, the healthcare sector continues to see a high frequency of cyberattacks and increasingly sophisticated threat actors, and our systems and the information maintained within those systems remain potentially vulnerable to data security incidents.

Any of the above-described cyber or other security-related incidents may trigger notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under foreign, federal, provincial and state laws that protect the privacy and security of personal information. Our proprietary and confidential information may also be accessed. Any one of these events could cause our business to be materially harmed and our results of operations may be adversely impacted. Finally, as cyber threats continue to evolve, and privacy and cybersecurity laws and regulations continue to develop, we may need to invest additional resources to implement new compliance measures, strengthen our information security posture, or respond to cyber threats and incidents.

We are subject to various internal control reporting requirements under the Sarbanes-Oxley Act. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.

As a public company, we are required to comply with Section 404 of the U.S.*Sarbanes-Oxley Act of 2002* ("Section 404"). In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board (U.S.) rules and regulations. Our management, including our chief executive officer and principal financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, as a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual consolidated financial statements will not be prevented or detected on a timely basis. If we fail to comply with the requirements of Section 404 or if we report a material weakness, we might be subject to regulatory sanction and investors may lose confidence in our consolidated financial statements, which may be inaccurate if we fail to remedy such material weakness.

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC and the Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

RISKS RELATED TO OUR PURSUIT OF STRATEGIC ALTERNATIVES

We may opportunistically review strategic transactions and there can be no assurance that that any such strategic transaction we may purse will result in additional value for our stockholders. As a result, the makeup of our lines of business may change.

We may from time to time assess alternate ways to generate value for shareholders, including reviewing opportunities that may lead to acquisitions, dispositions, business combinations or other strategic transactions. Strategies we may employ include seeking new or expanding existing specialty market niches, expanding our presence, acquiring businesses complementary to existing strengths and continually evaluating the performance and strategic fit of our existing business units. As a result, the makeup of our lines of business is subject to change. For example, as previously disclosed, in light of the unfavorable factors persistent in our rapid, point-of-care screening and testing product business and the progress we have made in our partnership with Premas, we conducted a strategic review of the screening and testing products business. Following such review, in early July 2020, we ceased the production and sale of our rapid, point-of-care screening and testing products. In connection with the discontinuation of our existing product line, we decided to close Thorofare Facility, which lease will terminate on December 13, 2020. We do not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. However, there can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

To the extent we engage in other strategic transactions, the process may be time consuming and disruptive to our business operations and, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with evaluating and negotiating potential strategic alternatives. Furthermore, our ability to effectively integrate any future acquisitions will depend on, among other things, the adequacy of our implementation plans, the ability of our management to oversee and operate effectively the combined operations and our ability to achieve desired operational efficiencies. If we are unable to successfully integrate the operations of any businesses that we may acquire in the future, our business, financial position, results of operations or cash flows could be adversely affected. There can be no assurance that any potential transaction, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock.

If we are unable to make acquisitions and investments, or successfully integrate them into our business, our business could be harmed.

As part of our business strategy, we may acquire other companies or businesses. However, we may not be able to find suitable acquisition candidates, and we may not be able to complete acquisitions on favorable terms, if at all. Acquisitions involve numerous risks, any of which could harm our business and negatively affect our operating results, including:

- difficulties in integrating the technologies, operations, existing contracts and personnel of an acquired company;
- difficulties in supporting and transitioning clients and suppliers, if any, of an acquired company;
- diversion of financial and management resources from existing operations or alternative acquisition opportunities;

- failure to realize the anticipated benefits or synergies of a transaction;
- failure to identify all of the problems, liabilities or other shortcomings or challenges of an acquired company or technology, including issues related to intellectual property, regulatory compliance practices, revenue recognition or other accounting practices, or employee or client issues;
- risks of entering new markets in which we have limited or no experience;
- potential loss of key employees, clients, vendors and suppliers from either our current business or an acquired company's business;
- inability to generate sufficient revenue to offset acquisition costs;
- additional costs or equity dilution associated with funding the acquisition; and
- possible write-offs or impairment charges relating to acquired businesses.

If we acquire a new business or retain individuals with expertise in a new industry to pursue a strategic alternative, we will have a limited operating history in such new industry and may not succeed.

We may from time to time assess alternative ways to generate value for shareholders, including reviewing opportunities in a new industry. If we acquire a new business or retain individuals with expertise in a new industry to pursue a strategic alternative, we will have a limited operating history within such new industry and may not succeed. We will be subject to all risks inherent in a developing business enterprise. The likelihood of our continued viability must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with manufacturing specialty products and the competitive and regulatory environment in which we operate. Furthermore, unanticipated expenses, problems, and technical difficulties may occur and they may result in material delays in the operation of our business, in particular with respect to our new products. We may not be able to successfully address these risks and uncertainties or successfully implement our operating strategies. If we fail to do so, such failure could materially harm our business to the point of having to cease operations and could impair the value of our common stock to the point investors may lose their entire investment.

RISKS RELATED TO THIS OFFERING AND OUR COMMON STOCK

The market price for our common stock may be volatile, and your investment in our common stock could decline in value.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or disapproval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical studies;
- developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;
- announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;
- public concerns as to the safety or efficacy of our products or our competitors' products;

- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- developments involving corporate collaborators, if any;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

Moreover, on March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic, and the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock. The delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on NASDAQ. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital and a minimum price per share. We cannot assure you that we will continue to meet the continued listing requirements in the future.

If NASDAQ delists our common stock from trading on its exchange, due to failure to meet its continued listing requirements, and we are not able to list our common stock on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our management team may invest or spend the proceeds raised in this offering in ways with which you may not agree or which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from this offering. We intend to use the net proceeds from this offering for general working capital and for corporate purposes. We have not allocated specific amounts of the net proceeds from this offering for any specific purpose. Accordingly, subject to any agreed upon contractual restrictions under the terms of the securities purchase agreement, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. You will be relying on the judgment of our management with regard to the use of these net proceeds, and subject to any agreed upon contractual restrictions under the terms of the purchase agreement, you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

You may experience immediate and substantial dilution.

Because the price per share of common stock being offered in this offering may be substantially higher than the net tangible book value per share of our common stock, you may experience substantial dilution to the extent of the difference between the effective offering price per share of common stock you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of March 31, 2020, was approximately $6.8 million, or $2.33 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding. See the section entitled "Dilution" on page S-38 below for a more detailed illustration of the dilution you may incur if you participate in this offering.

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

We may from time to time issue additional shares of common stock at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering from time to time, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales by our stockholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our Board and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our Board. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

We may issue additional series of preferred stock that rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference.

Neither our certificate of incorporation nor the Certificate of Designation for the Series C Preferred Stock prohibits us from issuing additional series of preferred stock that would rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference. Our certificate of incorporation provides that we have the authority to issue up to 50,000,000 shares of preferred stock, no shares of which are outstanding prior to this offering. The issuances of other series of preferred stock could have the effect of reducing the amounts available to the Series C Preferred Stock in the event of our liquidation, winding-up or dissolution. It may also reduce cash dividend payments on the Series C Preferred Stock if we do not have sufficient funds to pay dividends on all Series C Preferred Stock outstanding and outstanding parity preferred stock.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein and therein contain forward looking statements that involve risks and uncertainties. All statements other than statements of historical fact contained in this prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein and therein, including statements regarding future events, our future financial performance, business strategy, and plans and objectives of management for future operations, are forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Cystron, including:
  - the timing of, and our ability to, obtain and maintain regulatory approvals for clinical trials of our COVID-19 Vaccine Candidate;
  - the timing and results of our planned clinical trials for our COVID-19 Vaccine Candidate;
  - the amount of funds we require for our COVID-19 Vaccine Candidate; and
  - our ability to maintain our existing license with Premas.
- our ability to develop a COVID-Vaccine Candidate in a timely manner;
- our ability to effectively execute and deliver our plans related to commercialization, marketing and manufacturing capabilities and strategy;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain adequate financing in the future on reasonable terms, as and when we need it;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- the outcome of litigation or other proceedings to which we are subject as described in the "Legal Proceedings" sections of our annual report on Form 10-K filed with the SEC on March 25, 2020 and our subsequent filings with the SEC that are incorporated by reference to this prospectus supplement or which we may become subject to in the future;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate;
- delisting of our common stock from the NASDAQ capital market;
- our ability to protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on our proprietary rights;
- our compliance with all laws, rules, and regulations applicable to our business and COVID-19 Vaccine Candidate; and
- the impact of the recent COVID-19 outbreak on our results of operations, business plan and the global economy.

The foregoing does not represent an exhaustive list of risks that may impact upon the forward-looking statements used herein or in the documents incorporated by reference herein. For a more detailed discussion of such risks and other important factors that could cause actual results to differ materially from those in such forward-looking statements and forward-looking information, please see "Risk Factors" on page S-15 of this prospectus supplement and on page 6 of the accompanying base prospectus as well as the risk factors included in the documents incorporated herein and therein by reference. Although we have attempted to identify important factors that could cause actual results to differ materially from those described in forward-looking statements and forward-looking information, there may be other factors that cause results not to be as anticipated, estimated or intended. There can be no assurance that these statements will prove to be accurate as actual results and future events could differ materially from those anticipated in the statements. Except as required by law, we assume no obligation to publicly update any forward-looking statements and forward-looking information, whether as a result of new information, future events or otherwise. We qualify all forward-looking statements by these cautionary statements. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

DIVIDEND POLICY

We have not declared or paid any cash or other dividends on our capital stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board and will depend upon such factors as earnings levels, contractual restrictions, capital requirements, our overall financial condition and any other factors deemed relevant by our Board.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $6.2 million, after deducting the placement agent fees and estimated offering expenses payable by us.

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

Except as noted above, we have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering.

DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the price per share you pay in this offering and the as adjusted net tangible book value per share of our common stock after this offering, assuming no value is attributed to the warrants to be issued to the placement agent as compensation in connection with this offering.

Our net tangible book value as of March 31, 2020 was approximately $6.8 million, or $2.33 per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of March 31, 2020. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

Our pro forma net tangible book value as of March 31, 2020, after giving effect to (A) the issuance of 766,667 shares of our common stock at an offering price of $6.00 per share in the April Offering, after deducting placement agent fees and offering expenses paid by us in connection with the April Offering, (B) the payment of $250,000 of the net proceeds from the April Offering to the Sellers pursuant to the terms of the MIPA, (C) the issuance of 1,366,956 shares of common stock at an offering price of $3.53 per share in the May Offering, after deducting placement agent fees and offering expenses paid by us in connection with the May Offering, (D) the issuance of 1,885,000 shares of common stock upon the conversion of 1,885,000 shares of our Series C Convertible Preferred Stock issued upon exercise of warrants at an exercise price of $4.00 per share, (E) the issuance of 30,000 shares of common stock upon the exercise of pre-funded warrants at an exercise price of $0.0001 per share, (F) the issuance of 2,776 shares of common stock upon the conversion of 2,776 shares of our Series D Convertible Preferred Stock and (G) the issuance of 500,000 shares of common stock to ChubeWorkx pursuant to the SAGR, would have been approximately $22.5 million, or approximately $3.02 per share.

Our pro forma as adjusted net tangible book value as of March 31, 2020, after giving effect to our issuance and sale of 1,207,744 shares of common stock in this offering at the offering price of $5.67 per share, after deducting the placement agent fees and estimated offering expenses payable by us would have been $28.7 million, or $3.31 per share. This represents an immediate increase in pro forma as adjusted net tangible book value to existing stockholders of $0.29 per share and an immediate dilution to new investors purchasing securities in this offering of $2.36 per share.

The following table illustrates this per share dilution.

Offering price per share			$	5.67
Net tangible book value per share as of March 31, 2020	$	2.33		
Increase in pro forma net tangible book value per share	$	0.69		
Pro forma net tangible book value per share as of March 31, 2020	$	3.02		
Increase in pro forma as adjusted net tangible book value per share attributable to this offering	$	0.29		
Pro forma as adjusted net tangible book value per share as of March 31, 2020, after giving effect to this offering			$	3.31
Dilution per share to new investors purchasing our common stock in this offering			$	2.36

The above discussion and table are based on 2,915,240 shares outstanding as of March 31, 2020 and excludes as of that date:

- 247,215 shares of common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of $29.79 per share;
- 30,000 shares of common stock issuable upon the exercise of pre-funded warrants outstanding at a weighted average exercise price of $0.0001 per share;

- 40 shares of common stock issuable upon the exercise of options outstanding at a weighted average exercise price of $236.16 per share;
- 15,603 shares of common stock issuable upon the vesting of restricted stock units;
- 67,959 shares of common stock available for future issuance under our equity compensation plans;
- 211,353 shares of common stock issuable upon the conversion of the Series D Convertible Preferred Stock;
- 1,990,000 shares of common stock issuable upon the conversion of 1,990,000 shares of our Series C Convertible Preferred Stock issuable upon the exercise of warrants at an exercise price of $4.00 per share; and
- 96,620 shares of common stock issuable upon exercise of the placement agent warrants with an exercise price of $7.0875 to be issued to the placement agent as compensation in connection in this offering.

The foregoing discussion and table does not give effect to the accrued payments to the Sellers of $892,500.00 and $684,790.85 in connection with the May Offering and this offering, respectively, which will become due and payable on September 24, 2020, pursuant to the MIPA. For a more detailed discussion of the payments made to the Seller, see “Prospectus Supplement Summary” herein.

To the extent that outstanding exercisable options or warrants are exercised, you may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity or convertible debt securities, your ownership will be further diluted.

PLAN OF DISTRIBUTION

We engaged H.C. Wainwright & Co., LLC to act as our exclusive placement agent to solicit offers to purchase the shares of our common stock offered by this prospectus supplement and the accompanying base prospectus. Wainwright is not purchasing or selling any such shares, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of such shares, other than to use its "reasonable best efforts" to arrange for the sale of such shares by us. Therefore, we may not sell all of the shares of our common stock being offered. The terms of this offering were subject to market conditions and negotiations between us, Wainwright and prospective investors. Wainwright will have no authority to bind us by virtue of the engagement letter. We have entered into securities purchase agreements directly with certain institutional and accredited investors who have agreed to purchase shares of our common stock in this offering. We will only sell to investors who have entered into securities purchase agreements.

Delivery of the shares of common stock offered hereby is expected to take place on or about August 13, 2020, subject to satisfaction of certain customary closing conditions.

We have agreed to pay the placement agent (i) a total cash fee equal to 7.5% of the aggregate gross proceeds of this offering, (ii) a management fee equal to 1.0% of the aggregate gross proceeds of this offering, (iii) a non-accountable expense allowance of $50,000, and (iv) $12,900 for the clearing expenses of the placement agent in connection with this offering.

We estimate the total expenses of this offering paid or payable by us will be approximately $670,000. After deducting the fees due to the placement agent and our estimated expenses in connection with this offering, we expect the net proceeds from this offering will be approximately $6.2 million.

H.C. Wainwright & Co., LLC and one of its associated person of the placement agent has agreed to purchase in this offering, on the same terms and conditions, an aggregate of 119,564 shares of common stock for a total purchase price of approximately $677,928.

Placement Agent Warrants

In addition, we have agreed to issue to the placement agent, at the closing of this offering, warrants to purchase 8.0% of the number of shares of our common stock sold in this offering (or warrants to purchase up to 96,620 shares of our common stock), at an exercise price of $7.0875 per share (representing 125% of the offering price per share in this offering). Neither the placement agent's warrants nor the shares of our common stock issuable upon exercise thereof are being registered hereby.

The placement agent warrants will be exercisable immediately and for five years from the effective date of this offering. Pursuant to Rule 5110(g) of the Financial Industry Regulatory Authority, or FINRA, the placement agent's warrants and any shares issued upon exercise thereof will not be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person, for a period of 180 days immediately following the date of effectiveness or commencement of sales in this offering, except: (i) the transfer of any security by operation of law or by reason of our reorganization; (ii) the transfer of any security to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) the transfer of any security if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) the transfer of any security that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act") and liabilities arising from breaches of representations and warranties contained in our engagement letter with the placement agent. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

In addition, we will indemnify the purchaser of shares of our common stock in this offering against liabilities arising out of or relating to (i) any breach of any of the representations, warranties, covenants or agreements made by us in the securities purchase agreement or related documents or (ii) any action instituted against a purchaser by a third party (other than a third party who is affiliated with such purchaser) with respect to the securities purchase agreement or related documents and the transactions contemplated thereby, subject to certain exceptions.

Tail Financing Payments

We have also agreed to pay Wainwright, subject to certain exceptions, a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to the Company by Wainwright during the term of its engagement or introduced to us by Wainwright during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following the expiration or termination of the engagement letter.

Other Relationships

From time to time, Wainwright may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. The Placement Agent acted as our placement agent for the April Offering, the May Offering and the public offering we consummated in December 2019, for which it received compensation. In addition, each of the two entities that own approximately one-third of Cystron is controlled by an associated person of the placement agent (the "Associated Persons"). The Associated Persons received consideration pursuant to the MIPA in connection with the April Offering and the May 2020 Offering. The closing of this offering will trigger an accrued payment to the Associated Persons of approximately $228,263.62 pursuant to the MIPA, which will be due and payable, along with approximately $297,000 in connection with the April Offering, on September 24, 2020. However, except as disclosed in this prospectus supplement, we have no present arrangements with Wainwright for any further services.

Regulation M Compliance

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the sale of our shares of common stock offered hereby by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Trading Market

Our common stock is listed on The Nasdaq Capital Market under the symbol "AKER."

LEGAL MATTERS

The validity of the securities offered by this prospectus supplement has been passed upon for us by Haynes and Boone, LLP, New York, New York.

EXPERTS

The consolidated financial statements of Akers Biosciences, Inc. and subsidiaries as of December 31, 2019 and December 31, 2018, and for each of the two years in the period ended December 31, 2019, incorporated in this prospectus supplement by reference to the Annual Report on Form 10-K for the year ended December 31, 2019, have so incorporated in reliance on the report of Morison Cogen LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION; INFORMATION INCORPORATED BY REFERENCE

Available Information

We have filed with the SEC a registration statement on Form S-3 under the Securities Act, of which this prospectus supplement forms a part. The rules and regulations of the SEC allow us to omit from this prospectus supplement and the accompanying prospectus certain information included in the registration statement. For further information about us and the securities we are offering under this prospectus supplement, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus supplement and the accompanying prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement.

We file reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of the SEC's website is www.sec.gov.

We make available free of charge on or through our website at www.AkersBio.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the SEC. The information on, or accessible through, our website is not part of, and is not incorporated into, this prospectus supplement or the accompanying prospectus and should not be considered part of this prospectus supplement or the accompanying prospectus.

Incorporation by Reference

The SEC's rules allow us to "incorporate by reference" information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus supplement and the accompanying prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus supplement and accompanying prospectus to the extent that a statement contained in this prospectus supplement or the accompanying prospectus modifies or replaces that statement.

We incorporate by reference our documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act in this prospectus supplement, between the date of this prospectus supplement and the termination of the offering of the securities described in this prospectus supplement. We are not, however, incorporating by reference any documents or portions thereof, whether specifically listed below or filed in the future, that are not deemed "filed" with the SEC, including our Compensation Committee report and performance graph or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K.

This prospectus supplement and the accompanying prospectus incorporate by reference the documents set forth below that have previously been filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 24, 2020;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 15, 2020;
- Our Definitive Proxy Statement on Schedule 14A, filed with the SEC on July 29, 2020;
- Current Reports on Form 8-K filed on with the SEC on January 6, 2020, January 31, 2020, March 24, 2020, April 7, 2020, April 8, 2020, April 14, 2020, April 17, 2020, May 14, 2020, May 15, 2020, May 18, 2020, May 19, 2020, July 8, 2020, July 13, 2020, July 22, 2020, July 27, 2020 and August 7, 2020; and
- The description of our common stock contained in our Registration Statement on Form 8-A, filed on January 17, 2014 pursuant to Section 12(b) of the Exchange Act, which incorporates by reference the description of the shares of our common stock contained in the section entitled "Description of Securities" in our Registration Statement on Form S-1 (File No. 333-190456), as initially filed with the SEC on August 7, 2013, as amended, and any amendment or report filed with the SEC for purposes of updating such description.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus supplement and the accompanying prospectus and deemed to be part of this prospectus supplement and the accompanying prospectus from the date of the filing of such reports and documents.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date of this prospectus supplement or the date of the documents incorporated by reference in this prospectus supplement.

You may request a free copy of any of the documents incorporated by reference in this prospectus supplement and the accompanying prospectus (other than exhibits, unless they are specifically incorporated by reference in the documents) by writing or telephoning us at the following address:

Akers Biosciences, Inc.
201 Grove Road, Thorofare
New Jersey USA 08086
(856) 848-8698
Attn: Investor Relations

You may also access the documents incorporated by reference in this prospectus through our website at www.AkersBio.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

Prospectus

$25,000,000

COMMON STOCK
PREFERRED STOCK
WARRANTS
DEBT SECURITIES
UNITS

- common stock;
- preferred stock;
- warrants to purchase our securities;
- secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities; or
- units comprised of, or other combinations of, the foregoing securities.

We may offer and sell these securities separately or together, in one or more series or classes and in amounts, at prices and on terms described in one or more offerings. We may offer securities through underwriting syndicates managed or co-managed by one or more underwriters or dealers, through agents or directly to purchasers. The prospectus supplement for each offering of securities will describe in detail the plan of distribution for that offering. For general information about the distribution of securities offered, please see "Plan of Distribution" in this prospectus.

Each time our securities are offered, we will provide a prospectus supplement containing more specific information about the particular offering and attach it to this prospectus. The prospectus supplements may also add, update or change information contained in this prospectus. **This prospectus may not be used to offer or sell securities without a prospectus supplement which includes a description of the method and terms of this offering.**

Our common stock is quoted on the NASDAQ Capital Market under the symbol "AKER." The last reported sale price of our common stock on the NASDAQ Capital Market on April 6, 2020, was $4.69 per share. The aggregate market value of our outstanding common stock held by non-affiliates is $13,663,672 based on 2,915,240 shares of outstanding common stock, of which 2,913,363 shares are held by non-affiliates, and a per share price of $4.69 which was the closing sale price of our common stock as quoted on the NASDAQ Capital Market on April 6, 2020. During the 12 calendar month period that ends on, and includes, the date of this prospectus, we have not offered and sold any of our securities pursuant to General Instruction I.B.6 of Form S-3.

If we decide to seek a listing of any preferred stock, warrants, debt securities or units offered by this prospectus, the related prospectus supplement will disclose the exchange or market on which the securities will be listed, if any, or where we have made an application for listing, if any.

Investing in our securities involves certain risks. See "Risk Factors" beginning on page 6 and the risk factors in our most recent Annual Report on Form 10-K, which is incorporated by reference herein, as well as in any other recently filed quarterly or current reports and, if any, in the relevant prospectus supplement. We urge you to carefully read this prospectus and the accompanying prospectus supplement, together with the documents we incorporate by reference, describing the terms of these securities before investing.

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

The date of this Prospectus is April 7, 2020

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may offer and sell, either individually or in combination, in one or more offerings, any of the securities described in this prospectus, for total gross proceeds of up to $25,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities under this prospectus, we will provide a prospectus supplement to this prospectus that will contain more specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change any of the information contained in this prospectus or in the documents that we have incorporated by reference into this prospectus.

We urge you to read carefully this prospectus, any applicable prospectus supplement and any free writing prospectuses we have authorized for use in connection with a specific offering, together with the information incorporated herein by reference as described under the heading "Incorporation of Documents by Reference," before investing in any of the securities being offered. You should rely only on the information contained in, or incorporated by reference into, this prospectus and any applicable prospectus supplement, along with the information contained in any free writing prospectuses we have authorized for use in connection with a specific offering. We have not authorized anyone to provide you with different or additional information. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so.

The information appearing in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security.

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

This prospectus contains, or incorporates by reference, trademarks, tradenames, service marks and service names of Akers Biosciences, Inc.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus and any accompanying prospectus supplement and the documents we have filed or will file with the SEC that are or will be incorporated by reference into this prospectus and the accompanying prospectus supplement contain forward-looking statements, within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties. Any statements contained, or incorporated by reference, in this prospectus and any accompanying prospectus that are not statements of historical fact may be forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements.

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- changes in the market acceptance of our products and services;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- the outcome of ongoing litigation or other proceedings or which we may become subject to in the future;
- increased levels of competition;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate;
- our relationships with our key customers;
- adverse conditions in the industries in which our customers operate;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- delisting of our common stock from the NASDAQ capital market;
- our ability to protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on our proprietary rights;
- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Cystron Biotech, LLC; and
- other risks, including those described in the "Risk Factors" discussion of this prospectus.

The foregoing does not represent an exhaustive list of risks that may impact upon the forward-looking statements used herein or in the documents incorporated by reference herein. Please see "Risk Factors" in our reports filed with the SEC or in a prospectus supplement related to this prospectus for additional risks which could adversely impact our business and financial performance. Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this prospectus and any accompanying prospectus supplement are based on information available to us on the date hereof or thereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout (or incorporated by reference in) this prospectus, any accompanying prospectus and the documents we have filed with the SEC.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before investing in our Company. You should carefully read the entire prospectus, including all documents incorporated by reference herein. In particular, attention should be directed to our "Risk Factors," "Information With Respect to the Company," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto contained herein or otherwise incorporated by reference hereto, before making an investment decision.

As used herein, and any amendment or supplement hereto, unless otherwise indicated, "we," "us," "our," the "Company," "Akers" or similar terminology means Akers Biosciences, Inc.

Overview

We develop, manufacture, and supply rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a timely and cost-efficient manner. We believe that we have advanced the science of diagnostics through the development of several proprietary platform technologies. Our current product offerings focus on delivering diagnostic assistance in a variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin and for on- and off-the-job alcohol safety initiatives.

Recent Developments

Progress in Our Vaccine Development for COVID-19

Pursuant to the License Agreement, as discussed below, as of April 6, 2020, our collaboration with Premas has successfully completed the milestone of obtaining clones of all three COVID-19 antigens, Spike (S), Envelope (E) and Membrane (M) that we have selected for our vaccine candidate. The clone development process has four primary steps including first, the design and synthesis of the genes; second, the selection of the right host; third, the insertion of the gene into the host; and fourth, the verification that the clone has the right gene, and all characteristics are correct.

Acquisition of Cystron

On March 23, 2020, we entered into a Membership Interest Purchase Agreement (the "MIPA") with the members of Cystron Biotech, LLC (individually, each a "Seller," and collectively, the "Sellers"), pursuant to which the Company will acquire 100% of the membership interests (the "Membership Interests") of Cystron Biotech, LLC ("Cystron").

As consideration for the Membership Interests, we will deliver to the Sellers: (1) that number of newly issued shares of our common stock equal to 19.9% of the issued and outstanding shares of our common stock and pre-funded warrants as of the date of the MIPA, but, to the extent that the issuance of the our common stock would result in any Seller owning in excess of 4.9% of our outstanding common stock, then, at such Seller's election, such Seller may receive "common stock equivalent" preferred shares with a customary 4.9% blocker (with such common stock and preferred stock collectively referred to as "Common Stock Consideration"), and (2) $1,000,000 in cash.

Additionally, we shall (A) make an initial payment to the Sellers of up to $1,000,000 upon our receipt of cumulative gross proceeds from the consummation of an initial equity offering after the date of the MIPA of $8,000,000, and (B) pay to Sellers an amount in cash equal to 10% of the gross proceeds in excess of $8,000,000 raised from future equity offerings after the date of the MIPA until the Sellers have received an aggregate additional cash consideration equal to $10,000,000. Upon the achievement of certain milestones, including the completion of a Phase 2 study for a COVID-19 Vaccine that meets its primary endpoints, Sellers will be entitled to receive an additional 750,000 shares of our common stock or, in the event we are unable to obtain stockholder approval for the issuance of such shares, 750,000 shares of non-voting preferred stock that are valued following the achievement of such milestones and shall bear a 10% annual dividend (the "Milestone Shares"). Sellers will also be entitled to contingent payments from us of up to $20,750,000 upon the achievement of certain milestones, including the approval of a new drug application by the U.S. Food and Drug Administration ("FDA").

We shall also make quarterly royalty payments to Sellers equal to 5% of the net sales of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine") for a period of five (5) years following the first commercial sale of the COVID-19 Vaccine; provided, that such payment shall be reduced to 3% for any net sales of the COVID-19 Vaccine above $500 million.

In addition, Sellers shall be entitled to receive 12.5% of the transaction value, as defined in the MIPA, of any change of control transaction, as defined in the MIPA, that occurs prior to the fifth (5th) anniversary of the closing date of the MIPA, provided that the Company is still developing the COVID-19 Vaccine at that time. Following the consummation of any change of control transaction, the Sellers shall not be entitled to any payments as described above under the MIPA.

Support Agreement

On March 23, 2020, as an inducement to enter into the MIPA, and as one of the conditions to the consummation of the transactions contemplated by the MIPA, the Sellers entered into a shareholder voting agreement with the Company (the "Support Agreement"), pursuant to which each Seller agreed to vote their shares of our common stock or preferred stock in favor of each matter proposed and recommended for approval by our management at every meeting of the stockholders and on any action or approval by written consent of the stockholders.

Registration Rights Agreement

To induce the Sellers to enter into the MIPA, on March 23, 2020, we entered into a registration rights agreement (the "Registration Rights Agreement") with the Sellers, pursuant to which we shall by the 30th day following the closing of the transactions contemplated by the MIPA, file with the United States Securities and Exchange Commission (the "SEC") an initial Registration Statement on Form S-3 (if such form is available for use by the Company at such time) or, otherwise, on Form S-1, covering all of the shares of our common stock issued, or underlying the preferred stock issued, at closing under the MIPA and to subsequently register the common stock issued or underlying the preferred stock issued at Milestone Shares.

License Agreement

Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas Biotech PVT Ltd. ("Premas"). As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other corona virus infections.

Upon the achievement of certain developmental milestones by Cystron, Cystron shall pay to Premas a total of up to $2,000,000. *Series D Convertible Preferred Stock*

On March 24, 2020, we filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of New Jersey. Pursuant to the Certificate of Designation, in the event of the Company's liquidation or winding up of its affairs, the holders of our Series D Convertible Preferred Stock (the "Preferred Stock") will be entitled to receive the same amount that a holder of our common stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations set forth in the Certificate of Designation) to common stock which amounts shall be paid pari passu with all holders of the Company's common stock. Each share of Preferred Stock has a stated value equal to $0.01 (the "Stated Value"), subject to increase as set forth in Section 7 of the Certificate of Designation.

A holder of Preferred Stock is entitled at any time to convert any whole or partial number of shares of Preferred Stock into shares of our common stock determined by dividing the Stated Value of the Preferred Stock being converted by the conversion price of $0.01 per share.

A holder of Preferred Stock will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding (with such ownership restriction referred to as the "Beneficial Ownership Limitation"). However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

Subject to the Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of a meeting), each holder of Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of our common stock into which the shares of Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of our certificate of incorporation, the holders of Preferred Stock will vote together with the holders of our common stock and any other class or series of stock entitled to vote thereon as a single class.

A holder of Preferred Stock shall be entitled to receive dividends as and when paid to the holders of our common stock on an as-converted basis.

Production Backlog of PIFA® Heparin/PF4 and PIFA® Pluss/PF4

We are currently experiencing a production backlog of our PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays. While we believe that we will be able to remedy the production backlog, we cannot be certain what impact this backlog will have on our business and it may have an adverse effect on our 2020 revenues and results of operation.

Exploration of Strategic Alternatives

On November 7, 2018, we announced that our board of directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. The Company will continue its strategic alternatives review and has identified the hemp and minor cannabinoid sectors as potential opportunities that could benefit from our core competencies. The Company continues to explore how to leverage its 30 years of operational history in its medical device business, where its current products have FDA clearance, its current operations practice Good Manufacturing Processes (cGMP), its medical device facility is certified under ISO 13485 – 2016 and the facility carries an Analytical Lab Certification for Schedules 2, 3, 4 and 5 controlled substances issued by the U.S. Drug Enforcement Administration (DEA) and the State of New Jersey. The Company intends to pursue opportunities in the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry, including pathways to consumer products with a focus on minor cannabinoids.

Risks Associated with Our Business

Our business is subject to many significant risks, as more fully described in the section entitled "Risk Factors". You should read and carefully consider these risks, together with all of the other information in this prospectus, including the financial statements and the related notes included elsewhere in this prospectus, before deciding whether to invest in our securities. If any of the risks discussed in this prospectus actually occur, our business, financial condition or operating results could be materially and adversely affected. These risks include, but are not limited to, the following:

- we have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability;

- due to our dependence on a limited number of customers and the loss of any such customer would have a material adverse effect on our operating results and prospects;
- because we may not be able to maintain necessary regulatory clearances for some of our products, we may not generate revenue in the amounts we expect, or in the amounts necessary to continue our business;
- we are subject to regulations of various government agencies and if we are unable to comply with such regulations it would materially affect our business;
- modifications to our devices may require additional FDA approval which could force us to cease marketing and/or recall the modified device until we obtain new approvals;
- the Company's business would suffer if the Company were unable to acquire adequate sources of supply;
- our failure to regain and maintain compliance with the continued listing requirements of the NASDAQ Capital Market could result in a delisting of our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.; and
- we are currently subject to a number of litigations and we may be subject to similar other litigation in the future.

Corporate Information

We were incorporated in 1989 in the state of New Jersey. Our principal executive offices are located at 201 Grove Road, Thorofare, New Jersey USA 08086 and our telephone number is (856) 848-8698. Our corporate website address is *www.akersbio.com*. The information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which is incorporated herein by reference, as updated or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus and any prospectus supplement related to a particular offering. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled "Cautionary Statement Regarding Forward-Looking Statements."

USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, we intend to use the net proceeds from these sales for general corporate purposes or the acquisition of other businesses and working capital. The amounts and timing of these expenditures will depend on numerous factors, including the development of our current business initiatives. We have no specific acquisitions contemplated at this time.

PLAN OF DISTRIBUTION

We may sell the securities from time to time to or through underwriters or dealers, through agents, or directly to one or more purchasers. A distribution of the securities offered by this prospectus may also be effected through the issuance of derivative securities, including without limitation, warrants, rights to purchase and subscriptions. In addition, the manner in which we may sell some or all of the securities covered by this prospectus includes, without limitation, through:

- a block trade in which a broker-dealer will attempt to sell as agent, but may position or resell a portion of the block, as principal, in order to facilitate the transaction;
- purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account; or
- ordinary brokerage transactions and transactions in which a broker solicits purchasers.

A prospectus supplement or supplements with respect to each series of securities will describe the terms of the offering, including, to the extent applicable:

- the terms of the offering;
- the name or names of the underwriters or agents and the amounts of securities underwritten or purchased by each of them, if any;
- the public offering price or purchase price of the securities or other consideration therefor, and the proceeds to be received by us from the sale;
- any delayed delivery requirements;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any underwriting discounts or agency fees and other items constituting underwriters' or agents' compensation;
- any discounts or concessions allowed or re-allowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

The offer and sale of the securities described in this prospectus by us, the underwriters or the third parties described above may be effected from time to time in one or more transactions, including privately negotiated transactions, either:

- at a fixed price or prices, which may be changed;
- in an "at the market" offering within the meaning of Rule 415(a)(4) of the Securities Act;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

Underwriters and Agents; Direct Sales

If underwriters are used in a sale, they will acquire the offered securities for their own account and may resell the offered securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate.

Unless the prospectus supplement states otherwise, the obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

Dealers

We may sell the offered securities to dealers as principals. The dealer may then resell such securities to the public either at varying prices to be determined by the dealer or at a fixed offering price agreed to with us at the time of resale.

Institutional Purchasers

We may authorize agents, dealers or underwriters to solicit certain institutional investors to purchase offered securities on a delayed delivery basis pursuant to delayed delivery contracts providing for payment and delivery on a specified future date. The applicable prospectus supplement or other offering materials, as the case may be, will provide the details of any such arrangement, including the offering price and commissions payable on the solicitations.

We will enter into such delayed contracts only with institutional purchasers that we approve. These institutions may include commercial and savings banks, insurance companies, pension funds, investment companies and educational and charitable institutions.

Indemnification; Other Relationships

We may provide agents, underwriters, dealers and remarketing firms with indemnification against certain civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents, underwriters, dealers and remarketing firms, and their affiliates, may engage in transactions with, or perform services for, us in the ordinary course of business. This includes commercial banking and investment banking transactions.

Market-Making; Stabilization and Other Transactions

There is currently no market for any of the offered securities, other than our common stock, which is quoted on the NASDAQ Capital Market. If the offered securities are traded after their initial issuance, they may trade at a discount from their initial offering price, depending upon prevailing interest rates, the market for similar securities and other factors. While it is possible that an underwriter could inform us that it intends to make a market in the offered securities, such underwriter would not be obligated to do so, and any such market-making could be discontinued at any time without notice. Therefore, no assurance can be given as to whether an active trading market will develop for the offered securities. We have no current plans for listing of the debt securities, preferred stock or warrants on any securities exchange or quotation system; any such listing with respect to any particular debt securities, preferred stock or warrants will be described in the applicable prospectus supplement or other offering materials, as the case may be.

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters or agents that are qualified market makers on the NASDAQ Capital Market may engage in passive market making transactions in our common stock on the NASDAQ Capital Market in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of our common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Fees and Commissions

If 5% or more of the net proceeds of any offering of securities made under this prospectus will be received by a FINRA member participating in the offering or affiliates or associated persons of such FINRA member, the offering will be conducted in accordance with FINRA Rule 5121.

DESCRIPTION OF SECURITIES WE MAY OFFER

General

This prospectus describes the general terms of our capital stock. The following description is not complete and may not contain all the information you should consider before investing in our capital stock. For a more detailed description of these securities, you should read the applicable provisions of New Jersey law and our certificate of incorporation, as amended, referred to herein as our certificate of incorporation and our amended and restated bylaws, referred to herein as our bylaws. When we offer to sell a particular series of these securities, we will describe the specific terms of the series in a supplement to this prospectus. Accordingly, for a description of the terms of any series of securities, you must refer to both the prospectus supplement relating to that series and the description of the securities described in this prospectus. To the extent the information contained in the prospectus supplement differs from this summary description, you should rely on the information in the prospectus supplement.

The total number of shares of capital stock we are authorized to issue is 150,000,000 shares, of which (a) 100,000,000 are common stock and (b) 50,000,000 are preferred stock.

We, directly or through agents, dealers or underwriters designated from time to time, may offer, issue and sell, together or separately, up to $25,000,000 in the aggregate of:

- common stock;
- preferred stock;
- warrants to purchase our securities;
- secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities; or
- units comprised of, or other combinations of, the foregoing securities.

We may issue the debt securities exchangeable for or convertible into shares of common stock, preferred stock or other securities that may be sold by us pursuant to this prospectus or any combination of the foregoing. The preferred stock may also be exchangeable for and/or convertible into shares of common stock, another series of preferred stock or other securities that may be sold by us pursuant to this prospectus or any combination of the foregoing. When a particular series of securities is offered, a supplement to this prospectus will be delivered with this prospectus, which will set forth the terms of the offering and sale of the offered securities.

Common Stock

As of April 6, 2020, there were 2,915,240 shares of common stock issued and outstanding, held of record by approximately 760 stockholders. Subject to preferential rights with respect to any outstanding preferred stock, all outstanding shares of common stock are of the same class and have equal rights and attributes.

Voting Rights

Each Stockholder has one vote for each share of common stock held on all matters submitted to a vote of stockholders. A shareholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those shareholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation and bylaws provide that stockholder actions may be effected at a duly called meeting of stockholders or pursuant to written consent of the majority of shareholders. A special meeting of stockholders may be called by the President, Chief Executive Officer or the Board of Directors pursuant to a resolution approved by the majority of the Board of Directors.

Dividend Rights

The holders of outstanding shares of common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that our board may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. However, to date we have not paid or declared cash distributions or dividends on our common stock and do not currently intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain all earnings, if and when generated, to finance our operations. The declaration of cash dividends in the future will be determined by the board based upon our earnings, financial condition, capital requirements and other relevant factors.

No Preemptive or Similar Rights

Holders of our common stock do not have preemptive rights, and common stock is not convertible or redeemable.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders and remaining after payment to holders of preferred stock of the amounts, if any, to which they are entitled, are distributable ratably among the holders of our common stock subject to any senior class of securities.

Preferred Stock

Our certificate of incorporation empowers our board of directors, without action by our shareholders, to issue up to 50,000,000 shares of preferred stock from time to time in one or more series, which preferred stock may be offered by this prospectus and supplements thereto. As of April 6, 2020, there were 10,000,000 shares of preferred stock designated as Series A Preferred Stock, 1,990,000 shares of preferred stock designated as Series C Convertible Preferred Stock and 211,353 shares of preferred stock designated as Series D Preferred Stock. As of April 6, 2020, there were no shares of Series A Preferred Stock and Series C Convertible Stock issued and outstanding and 211,353 shares of Series D Preferred Stock issued and outstanding.

Our board may fix the rights, preferences, privileges, and restrictions of our authorized but undesignated preferred shares, including:

We will fix the rights, preferences, privileges and restrictions of the preferred stock of each series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. This description will include any or all of the following, as required:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- any contractual limitations on our ability to declare, set aside or pay any dividends;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;

- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

If we issue shares of preferred stock under this prospectus, after receipt of payment therefor, the shares will be fully paid and non-assessable.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our Company or make removal of management more difficult. Additionally, the issuance of preferred stock could have the effect of decreasing the market price of our common stock.

Warrants

We may issue warrants to purchase our securities or other rights, including rights to receive payment in cash or securities based on the value, rate or price of one or more specified commodities, currencies, securities or indices, or any combination of the foregoing. Warrants may be issued independently or together with any other securities that may be sold by us pursuant to this prospectus or any combination of the foregoing and may be attached to, or separate from, such securities. To the extent warrants that we issue are to be publicly-traded, each series of such warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the SEC, forms of the warrant and warrant agreement, if any. The prospectus supplement relating to any warrants that we may offer will contain the specific terms of the warrants and a description of the material provisions of the applicable warrant agreement, if any. These terms may include the following:

- the title of the warrants;
- the price or prices at which the warrants will be issued;
- the designation, amount and terms of the securities or other rights for which the warrants are exercisable;
- the designation and terms of the other securities, if any, with which the warrants are to be issued and the number of warrants issued with each other security;
- the aggregate number of warrants;
- any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;
- the price or prices at which the securities or other rights purchasable upon exercise of the warrants may be purchased;
- if applicable, the date on and after which the warrants and the securities or other rights purchasable upon exercise of the warrants will be separately transferable;
- a discussion of any material U.S. federal income tax considerations applicable to the exercise of the warrants;
- the date on which the right to exercise the warrants will commence, and the date on which the right will expire;
- the maximum or minimum number of warrants that may be exercised at any time;
- information with respect to book-entry procedures, if any; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Exercise of Warrants. Each warrant will entitle the holder of warrants to purchase the amount of securities or other rights, at the exercise price stated or determinable in the prospectus supplement for the warrants. Warrants may be exercised at any time up to the close of business on the expiration date shown in the applicable prospectus supplement, unless otherwise specified in such prospectus supplement. After the close of business on the expiration date, if applicable, unexercised warrants will become void. Warrants may be exercised in the manner described in the applicable prospectus supplement. When the warrant holder makes the payment and properly completes and signs the warrant certificate at the corporate trust office of the warrant agent, if any, or any other office indicated in the prospectus supplement, we will, as soon as possible, forward the securities or other rights that the warrant holder has purchased. If the warrant holder exercises less than all of the warrants represented by the warrant certificate, we will issue a new warrant certificate for the remaining warrants.

Debt Securities

As used in this prospectus, the term "debt securities" means the debentures, notes, bonds and other evidences of indebtedness that we may issue from time to time. The debt securities will either be senior debt securities, senior subordinated debt or subordinated debt securities. We may also issue convertible debt securities. Debt securities may be issued under an indenture (which we refer to herein as an Indenture), which are contracts entered into between us and a trustee to be named therein. The Indenture has been filed as an exhibit to the registration statement of which this prospectus forms a part. We may issue debt securities and incur additional indebtedness other than through the offering of debt securities pursuant to this prospectus. It is likely that convertible debt securities will not be issued under an Indenture.

The debt securities may be fully and unconditionally guaranteed on a secured or unsecured senior or subordinated basis by one or more guarantors, if any. The obligations of any guarantor under its guarantee will be limited as necessary to prevent that guarantee from constituting a fraudulent conveyance under applicable law. In the event that any series of debt securities will be subordinated to other indebtedness that we have outstanding or may incur, the terms of the subordination will be set forth in the prospectus supplement relating to the subordinated debt securities.

We may issue debt securities from time to time in one or more series, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities under the applicable Indenture and will be equal in ranking.

Should an Indenture relate to unsecured indebtedness, in the event of a bankruptcy or other liquidation event involving a distribution of assets to satisfy our outstanding indebtedness or an event of default under a loan agreement relating to secured indebtedness of our company or its subsidiaries, the holders of such secured indebtedness, if any, would be entitled to receive payment of principal and interest prior to payments on the unsecured indebtedness issued under an Indenture.

Each prospectus supplement will describe the terms relating to the specific series of debt securities. These terms will include some or all of the following:

- the title of debt securities and whether the debt securities are senior or subordinated;
- any limit on the aggregate principal amount of debt securities of such series;
- the percentage of the principal amount at which the debt securities of any series will be issued;
- the ability to issue additional debt securities of the same series;
- the purchase price for the debt securities and the denominations of the debt securities;
- the specific designation of the series of debt securities being offered;
- the maturity date or dates of the debt securities and the date or dates upon which the debt securities are payable and the rate or rates at which the debt securities of the series shall bear interest, if any, which may be fixed or variable, or the method by which such rate shall be determined;
- the basis for calculating interest;
- the date or dates from which any interest will accrue or the method by which such date or dates will be determined;

- the duration of any deferral period, including the period during which interest payment periods may be extended;
- whether the amount of payments of principal of (and premium, if any) or interest on the debt securities may be determined with reference to any index, formula or other method, such as one or more currencies, commodities, equity indices or other indices, and the manner of determining the amount of such payments;
- the dates on which we will pay interest on the debt securities and the regular record date for determining who is entitled to the interest payable on any interest payment date;
- the place or places where the principal of (and premium, if any) and interest on the debt securities will be payable, where any securities may be surrendered for registration of transfer, exchange or conversion, as applicable, and notices and demands may be delivered to or upon us pursuant to the applicable Indenture;
- the rate or rates of amortization of the debt securities;
- any terms for the attachment to the debt securities of warrants, options or other rights to purchase or sell our securities;
- if the debt securities will be secured by any collateral and, if so, a general description of the collateral and the terms and provisions of such collateral security, pledge or other agreements;
- if we possess the option to do so, the periods within which and the prices at which we may redeem the debt securities, in whole or in part, pursuant to optional redemption provisions, and the other terms and conditions of any such provisions;
- our obligation or discretion, if any, to redeem, repay or purchase debt securities by making periodic payments to a sinking fund or through an analogous provision or at the option of holders of the debt securities, and the period or periods within which and the price or prices at which we will redeem, repay or purchase the debt securities, in whole or in part, pursuant to such obligation, and the other terms and conditions of such obligation;
- the terms and conditions, if any, regarding the option or mandatory conversion or exchange of debt securities;
- the period or periods within which, the price or prices at which and the terms and conditions upon which any debt securities of the series may be redeemed, in whole or in part at our option and, if other than by a board resolution, the manner in which any election by us to redeem the debt securities shall be evidenced;
- any restriction or condition on the transferability of the debt securities of a particular series;
- the portion, or methods of determining the portion, of the principal amount of the debt securities which we must pay upon the acceleration of the maturity of the debt securities in connection with any event of default;
- the currency or currencies in which the debt securities will be denominated and in which principal, any premium and any interest will or may be payable or a description of any units based on or relating to a currency or currencies in which the debt securities will be denominated;
- provisions, if any, granting special rights to holders of the debt securities upon the occurrence of specified events;
- any deletions from, modifications of or additions to the events of default or our covenants with respect to the applicable series of debt securities, and whether or not such events of default or covenants are consistent with those contained in the applicable Indenture;
- any limitation on our ability to incur debt, redeem stock, sell our assets or other restrictions;
- the application, if any, of the terms of the applicable Indenture relating to defeasance and covenant defeasance (which terms are described below) to the debt securities;
- what subordination provisions will apply to the debt securities
- the terms, if any, upon which the holders may convert or exchange the debt securities into or for our securities or property;
- whether we are issuing the debt securities in whole or in part in global form;
- any change in the right of the trustee or the requisite holders of debt securities to declare the principal amount thereof due and payable because of an event of default;

- the depositary for global or certificated debt securities, if any;
- any material federal income tax consequences applicable to the debt securities, including any debt securities denominated and made payable, as described in the prospectus supplements, in foreign currencies, or units based on or related to foreign currencies;
- any right we may have to satisfy, discharge and defease our obligations under the debt securities, or terminate or eliminate restrictive covenants or events of default in the Indentures, by depositing money or U.S. government obligations with the trustee of the Indentures;
- the names of any trustees, depositories, authenticating or paying agents, transfer agents or registrars or other agents with respect to the debt securities;
- to whom any interest on any debt security shall be payable, if other than the person in whose name the security is registered, on the record date for such interest, the extent to which, or the manner in which, any interest payable on a temporary global debt security will be paid;
- if the principal of or any premium or interest on any debt securities is to be payable in one or more currencies or currency units other than as stated, the currency, currencies or currency units in which it shall be paid and the periods within and terms and conditions upon which such election is to be made and the amounts payable (or the manner in which such amount shall be determined);
- the portion of the principal amount of any debt securities which shall be payable upon declaration of acceleration of the maturity of the debt securities pursuant to the applicable Indenture;
- if the principal amount payable at the stated maturity of any debt security of the series will not be determinable as of any one or more dates prior to the stated maturity, the amount which shall be deemed to be the principal amount of such debt securities as of any such date for any purpose, including the principal amount thereof which shall be due and payable upon any maturity other than the stated maturity or which shall be deemed to be outstanding as of any date prior to the stated maturity (or, in any such case, the manner in which such amount deemed to be the principal amount shall be determined); and
- any other specific terms of the debt securities, including any modifications to the events of default under the debt securities and any other terms which may be required by or advisable under applicable laws or regulations.

Unless otherwise specified in the applicable prospectus supplement, we do not anticipate the debt securities will be listed on any securities exchange. Holders of the debt securities may present registered debt securities for exchange or transfer in the manner described in the applicable prospectus supplement. Except as limited by the applicable Indenture, we will provide these services without charge, other than any tax or other governmental charge payable in connection with the exchange or transfer.

Debt securities may bear interest at a fixed rate or a variable rate as specified in the prospectus supplement. In addition, if specified in the prospectus supplement, we may sell debt securities bearing no interest or interest a t a rate that at the time of issuance is below the prevailing market rate, or at a discount below their stated principal amount. We will describe in the applicable prospectus supplement any special federal income tax considerations applicable to these discounted debt securities.

We may issue debt securities with the principal amount payable on any principal payment date, or the amount of interest payable on any interest payment date, to be determined by referring to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such debt securities may receive a principal amount on any principal payment date, or interest payments on any interest payment date, that are greater or less than the amount of principal or interest otherwise payable on such dates, depending upon the value on such dates of applicable currency, commodity, equity index or other factors. The applicable prospectus supplement will contain information as to how we will determine the amount of principal or interest payable on any date, as well as the currencies, commodities, equity indices or other factors to which the amount payable on that date relates and certain additional tax considerations.

Units

We may issue units consisting of any combination of the other types of securities offered under this prospectus in one or more series. We may evidence each series of units by unit certificates that we may issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent, if any, may be a bank or trust company that we select. We will indicate the name and address of the unit agent, if any, in the applicable prospectus supplement relating to a particular series of units. Specific unit agreements, if any, will contain additional important terms and provisions. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report that we file with the SEC, the form of unit and the form of each unit agreement, if any, relating to units offered under this prospectus.

If we offer any units, certain terms of that series of units will be described in the applicable prospectus supplement, including, without limitation, the following, as applicable:

- the title of the series of units;
- identification and description of the separate constituent securities comprising the units;
- the price or prices at which the units will be issued;
- the date, if any, on and after which the constituent securities comprising the units will be separately transferable;
- a discussion of certain United States federal income tax considerations applicable to the units; and
- any other material terms of the units and their constituent securities.

Anti-Takeover Provisions

The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us.

These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

FORMS OF SECURITIES

Each security may be represented either by a certificate issued in definitive form to a particular investor or by one or more global securities representing the entire issuance of securities. Certificated securities in definitive form and global securities will be issued in registered form. Definitive securities name you or your nominee as the owner of the security, and in order to transfer or exchange these securities or to receive payments other than interest or other interim payments, you or your nominee must physically deliver the securities to the trustee, registrar, paying agent or other agent, as applicable. Global securities name a depositary or its nominee as the owner of the debt securities, warrants or units represented by these global securities. The depositary maintains a computerized system that will reflect each investor's beneficial ownership of the securities through an account maintained by the investor with its broker/dealer, bank, trust company or other representative, as we explain more fully below.

Registered Global Securities

We may issue the securities in the form of one or more fully registered global securities that will be deposited with a depositary or its nominee identified in the applicable prospectus supplement and registered in the name of that depositary or nominee. In those cases, one or more registered global securities will be issued in a denomination or aggregate denominations equal to the portion of the aggregate principal or face amount of the securities to be represented by registered global securities. Unless and until it is exchanged in whole for securities in definitive registered form, a registered global security may not be transferred except as a whole by and among the depositary for the registered global security, the nominees of the depositary or any successors of the depositary or those nominees.

The specific terms of the depositary arrangement with respect to any securities to be represented by a registered global security will be described in the prospectus supplement relating to those securities. We anticipate that the following provisions will apply to all depositary arrangements.

Ownership of beneficial interests in a registered global security will be limited to persons, called participants, that have accounts with the depositary or persons that may hold interests through participants. Upon the issuance of a registered global security, the depositary will credit, on its book-entry registration and transfer system, the participants' accounts with the respective principal or face amounts of the securities beneficially owned by the participants. Any dealers, underwriters or agents participating in the distribution of the securities will designate the accounts to be credited. Ownership of beneficial interests in a registered global security will be shown on, and the transfer of ownership interests will be effected only through, records maintained by the depositary, with respect to interests of participants, and on the records of participants, with respect to interests of persons holding through participants. The laws of some states may require that some purchasers of securities take physical delivery of these securities in definitive form. These laws may impair your ability to own, transfer or pledge beneficial interests in registered global securities.

So long as the depositary, or its nominee, is the registered owner of a registered global security, that depositary or its nominee, as the case may be, will be considered the sole owner or holder of the securities represented by the registered global security for all purposes under the applicable indenture, warrant agreement or unit agreement.

Except as described below, owners of beneficial interests in a registered global security will not be entitled to have the securities represented by the registered global security registered in their names, will not receive or be entitled to receive physical delivery of the securities in definitive form and will not be considered the owners or holders of the securities under the applicable indenture, warrant agreement or unit agreement. Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depositary for that registered global security and, if that person is not a participant, on the procedures of the participant through which the person owns its interest, to exercise any rights of a holder under the applicable indenture, warrant agreement or unit agreement. We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take any action that a holder is entitled to give or take under the applicable indenture, warrant agreement or unit agreement, the depositary for the registered global security would authorize the participants holding the relevant beneficial interests to give or take that action, and the participants would authorize beneficial owners owning through them to give or take that action or would otherwise act upon the instructions of beneficial owners holding through them.

Payments to holders with respect to securities represented by a registered global security registered in the name of a depositary or its nominee will be made to the depositary or its nominee, as the case may be, as the registered owner of the registered global security. None of the Company, the trustees, the warrant agents, the unit agents or any other agent of the Company, agent of the trustees, the warrant agents or unit agents will have any responsibility or liability for any aspect of the records relating to payments made on account of beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to those beneficial ownership interests.

We expect that the depositary for any of the securities represented by a registered global security, upon receipt of any payment of principal, premium, interest or other payment or distribution to holders of that registered global security, will immediately credit participants' accounts in amounts proportionate to their respective beneficial interests in that registered global security as shown on the records of the depositary. We also expect that payments by participants to owners of beneficial interests in a registered global security held through participants will be governed by standing customer instructions and customary practices, as is now the case with the securities held for the accounts of customers or registered in "street name," and will be the responsibility of those participants.

If the depositary for any of these securities represented by a registered global security is at any time unwilling or unable to continue as depositary or ceases to be a clearing agency registered under the Exchange Act and a successor depositary registered as a clearing agency under the Exchange Act is not appointed by us within 90 days, we will issue securities in definitive form in exchange for the registered global security that had been held by the depositary. Any securities issued in definitive form in exchange for a registered global security will be registered in the name or names that the depositary gives to the relevant trustee, warrant agent, unit agent or other relevant agent of ours or theirs. It is expected that the depositary's instructions will be based upon directions received by the depositary from participants with respect to ownership of beneficial interests in the registered global security that had been held by the depositary.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered by this prospectus will be passed upon for us by Haynes and Boone, LLP, New York, New York. If legal matters in connection with offerings made by this prospectus are passed on by counsel for the underwriters, dealers or agents, if any, that counsel will be named in the applicable prospectus supplement.

EXPERTS

Morison Cogen LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed on March 24, 2020, as set forth in their report which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our consolidated financial statements are incorporated by reference in reliance on Morison Cogen LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarter and periodic reports, proxy statements and other information with the Securities and Exchange Commission using the Commission's EDGAR system. The Commission maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission. The address of such site is http//www.sec.gov.

INCORPORATION OF DOCUMENTS BY REFERENCE

We are "incorporating by reference" in this prospectus certain documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus. Statements contained in documents that we file with the SEC and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. We have filed or may file the following documents with the SEC and they are incorporated herein by reference as of their respective dates of filing.

1. Our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 24, 2020;
2. Our Current Reports on Form 8-K filed with the SEC on January 6, 2020, January 31, 2020, and March 24, 2020 (other than any portions thereof deemed furnished and not filed); and
3. The description of our common stock contained in our Registration Statement on Form 8-A, filed on January 17, 2014 pursuant to Section 12(b) of the Exchange Act, which incorporates by reference the description of the shares of our common stock contained in the section entitled "Description of Securities" in our Registration Statement on Form S-1 (File No. 333-190456), as initially filed with the SEC on August 7, 2013, as amended, and any amendment or report filed with the SEC for purposes of updating such description.

All documents that we filed with the SEC pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus, or in any subsequently filed document that also is deemed to be incorporated by reference in this prospectus, modifies, supersedes or replaces such statement. Any statement so modified, superseded or replaced shall not be deemed, except as so modified, superseded or replaced, to constitute a part of this prospectus. None of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K or any corresponding information, either furnished under Item 9.01 or included as an exhibit therein, that we may from time to time furnish to the SEC will be incorporated by reference into, or otherwise included in, this prospectus, except as otherwise expressly set forth in the relevant document. Subject to the foregoing, all information appearing in this prospectus is qualified in its entirety by the information appearing in the documents incorporated by reference.

You may requests, orally or in writing, a copy of these documents, which will be provided to you at no cost (other than exhibits, unless such exhibits are specifically incorporate by reference), by contacting Akers Biosciences, Inc., at 201 Grove Road, Thorofare, New Jersey 08086. Our telephone number is (856) 848-8698. Information about us is also available at our website at http://www.akersbio.com. However, the information in our website is not a part of this prospectus and is not incorporated by reference.

1,207,744 Shares

AKERS BIOSCIENCES, INC.

Common Stock

PROSPECTUS SUPPLEMENT

H.C. Wainwright & Co.

August 11, 2020