PROSPECTUS

**Filed Pursuant to Rule 424(b)(4)**
**Registration Nos. 333-234447 and 333-235359**

# 613,500 Class A Units consisting of Common Stock and Warrants or 1,376,500 Class B Units consisting of Pre-funded Warrants and Warrants 1,376,500 Shares of Common Stock Underlying the Pre-funded Warrants and 1,990,000 shares of Series C Convertible Preferred Stock Underlying the Warrants


We are offering 613,500 Class A Units with each Class A Unit consisting of one share of our common stock and one warrant to purchase one share of our Series C Convertible Preferred Stock, or the Series C Preferred Stock, at an exercise price of $4.00 per share, or an investor warrant. The Class A Units will not be certificated and the share of common stock and the investor warrant comprising such unit are immediately separable and will be issued separately in this offering.

We are also offering 1,376,500 Class B Units to those purchasers, whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, in lieu of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%), with each Class B Unit consisting of one pre-funded warrant to purchase one share of our common stock, or a pre-funded warrant, and one investor warrant to purchase one share of Series C Preferred Stock. The purchase price for each Class B Unit is equal the public offering price per Class A Unit in this offering less the $0.0001 per share exercise price of the pre-funded warrant included in the Class B Unit, and the exercise price of each pre-funded warrant is equal $0.0001 per share. We are also offering the shares of common stock that are issuable from time to time upon exercise of the pre-funded warrants being offered by this prospectus. The Class B Units will not be certificated and the pre-funded warrants and the investor warrants comprising such unit are immediately separable and will be issued separately in this offering. Each purchase of Class B Units in this offering will reduce the number of Class A Units in this offering on a one-for-one basis.

The investor warrants contained in the Class A and the Class B Units (collectively, the "Units") will be exercisable immediately and will expire on the five year anniversary of the date (the "Charter Amendment Date") on which we publicly announce through the filing of a Current Report on Form 8-K that the amendment to our certificate of incorporation to sufficiently increase our authorized shares of common stock to cover the conversion of all shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock has been filed with the Secretary of State of the State of New Jersey.

We are also offering the shares of Series C Preferred Stock that are issuable from time to time upon exercise of the warrants contained in the Units at $4.00 per Series C Preferred Stock. We do not currently have a sufficient number of authorized shares of common stock to cover the shares issuable upon the conversion of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering. Before any shares of Series C Preferred Stock can become convertible, we need to receive stockholder approval of an amendment (the "Charter Amendment") to our amended and restated certificate of incorporation, as amended, to sufficiently increase our authorized shares of common stock to cover the conversion of all shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock. We have agreed in the securities purchase agreement for this offering to use our reasonable best efforts to obtain such approval within 60 days from the date of this prospectus. We intend to seek stockholder approval to amend our amended and restated certificate of incorporation, as amended, to increase the number of authorized shares of common stock from 2,604,167 to 100,000,000 shares at our 2019 annual meeting of stockholders scheduled to be held on December 30, 2019. We cannot assure you that we will be able to obtain requisite stockholder approval of the Charter Amendment. The Series C Preferred Stock will not be convertible until the next business day after the Charter Amendment Date at which time each one share of the Series C Preferred Stock will be convertible into one share of common stock. In the event that our stockholders do not approve the Charter Amendment, the Series C Preferred Stock will not be convertible into common stock and the value of the warrants and the Series C Preferred Stock will be negatively affected.

Our common stock is currently traded on the NASDAQ under the symbol "AKER". On December 5, 2019, the last reported sale price of our common stock as reported on NASDAQ was $3.16 per share. There is no public trading market for the pre-funded warrants, investor warrants or Series C Preferred Stock and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants, investor warrants or Series C Preferred Stock on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants, investor warrants and Series C Preferred Stock will be limited.

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

We are an "emerging growth company" as the term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

**Investing in our securities involves risks that are described in the "Risk Factors" beginning on page 10 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.**

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

| | Per Class A Unit | Per Class B Unit | Total |
|---|---|---|---|
| Public offering price | $ 4.00 | $ 3.9999 | $ 7,959,862.35 |
| Placement agent's fees[1] | $ 0.30 | $ 0.3000 | $ 597,000 |
| Proceeds, before expenses, to us | $ 3.70 | $ 3.6999 | $ 7,362,862.35 |

(1) In addition, we have agreed to reimburse the placement agent certain offering-related expenses, including a management fee of 1% of the gross proceeds raised in this offering, and to issue the placement agent or its designees warrants to purchase up to 159,200 shares of common stock. See "Plan of Distribution" beginning on page 51 of this prospectus for a description of compensation payable to the placement agent.

We have retained H.C. Wainwright & Co., LLC as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities in this

offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent's fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above.

Delivery of the securities is expected on or about December 9, 2019, subject to satisfaction of certain conditions.

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

**Prospectus dated December 5, 2019**

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Please read this prospectus carefully. It describes our business, our financial condition and our results of operations. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision. You should rely only on the information contained in or incorporated by reference in this prospectus. We have not authorized anyone to provide you with any information or to make any representations about us, the securities being offered pursuant to this prospectus or any other matter discussed in this prospectus, other than the information and representations contained in this prospectus and the documents incorporated by reference. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us.

The information appearing or incorporated by reference in this prospectus is accurate only as of the date of this prospectus or the date of the applicable document incorporated by reference. Neither the delivery of this prospectus nor any distribution of securities in accordance with this prospectus shall, under any circumstances, imply that there has been no change in our affairs since the date of this prospectus. This prospectus will be updated and made available for delivery to the extent required by the federal securities laws.

This prospectus and documents incorporated by reference in this prospectus include estimates, statistics and other industry data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

On November 25, 2019, we amended our amended and restated certificate of incorporation, as amended, to effect a 1-for-24 reverse split of our authorized and outstanding and issued shares of our common stock. All share and per share data in this prospectus gives effect to the reverse stock split. Documents incorporated by reference into this prospectus that were filed prior to November 25, 2019, do not give effect to the reverse stock split.

## PROSPECTUS SUMMARY

*This summary highlights information contained in other parts of this prospectus and in the documents incorporated by reference. Because it is a summary, it does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this prospectus and the documents incorporated by reference in their entirety including the information described under "Risk Factors" in this prospectus and the financial statements and the notes to those financial statements incorporated by reference in this prospectus before investing in our securities. See information set forth under the section "Cautionary Note Regarding Forward-Looking Statements." Unless the context provides otherwise, all references herein to "Akers", "ABI", "Akers Bio", the "Company", "we", "our" and "us" refer to 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. The Company's 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.

All of our rapid, single-use tests are performed in vitro (outside the body) and are designed to enhance patient well-being and reduce the cost of healthcare. The Company's current product offerings focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform. PIFA® technology is a patented immunoassay method which rapidly and accurately detects target antigens or antibodies. It is the technology platform utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. We have determined that it is not economically appropriate to further develop or pursue approval of the PIFA PLUSS Chlamydia Rapid Assay device. As of September 30, 2019, the Company's marketed products consist only of its PIFA® Heparin/PF4, PIFA PLUSS® PF4 and BreathScan Alcohol Detectors.

We believe that low-cost, single-use testing not only saves time and money, but allows for more frequent, near-patient testing which may save lives. We believe that our FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment.

We believe the use of rapid tests, which can be performed at the point-of-care when and where the patient is being consulted, can result in immediate diagnostic decisions and subsequent treatment regimens and is an important development in the practice of medicine. Point-of-care testing addresses today's challenges in the healthcare industry, such as:

- cost pressures/efficiency of healthcare delivery; and
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness

*Strategy*

Akers' strategy for the medical device business is to leverage where possible its distributor relationships, while exploring strategies for further reducing its costs.

Akers has developed and currently maintains strategic relationships with established companies that are in the clinical laboratory market.

**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;
- we will require additional capital in the future to support our operations or to pursue strategic alternative transactions, which we may not be able to secure when needed on acceptable terms, or at all, and may be dilutive to our stockholders;
- 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.

**Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies. The Company is expected to lose its EGC status on December 31, 2019 as it is the last day of the fiscal year following the fifth anniversary of the effective date of its registration statement on January 23, 2014. These provisions include, but are not limited to:

- being permitted to have only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure;
- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements and proxy statements; and
- exemptions from the requirements to seek non-binding advisory votes on executive compensation or golden parachute arrangements.

In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We chose to "opt out" of this provision. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of our initial public offering, (ii) the first fiscal year after our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.

**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.

**Recent Developments**

***Board's Evaluation of Strategic Alternatives***

On November 7, 2018, the Company announced that its Board of Directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. This process is ongoing and the Company is considering a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. On November 19, 2018, the Company further announced that in its evaluation of strategic alternatives it will consider a range of potential strategic alternatives including, but not limited to, business combinations in sectors different than that currently engaged in, including cannabis and hemp related industries. The Board of Directors may also pursue a strategic alternative in one of the aforementioned industries by retaining individuals that have expertise in those industries. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

Further to the Company's pursuit of strategic alternatives, pursuant to an unsecured promissory note dated July 4, 2019, on July 25, 2019 the Company advanced $100,000 to a company in the hemp related industry with which the Company had been considering a potential business transaction. Discussions with this party toward a potential transaction have been suspended. The unsecured promissory note became due on October 2, 2019 and the Company is pursuing collection of the obligation.

On December 4, 2019, the Board of Directors of the Company formed an advisory board (the "Advisory Board") with expertise in the hemp and minor cannabinoid. The Company will continue its strategic alternatives review and has identified the hemp and minor cannabinoid sectors as potential opportunities that could benefit from Akers' core competencies. The Company is exploring how to leverage its 30 years of operational history in its medical device business, where its current products have U.S. Food and Drug Administration (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 Advisory Board will assist the Board of Directors in its strategic review including, potentially, the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry. The Advisory Board may also explore a pathway to consumer products with a focus on minor cannabinoids.

***NASDAQ Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing***

On May 10, 2019, the Company received notification (the "Letter") from the Nasdaq Listing Qualifications Department of The Nasdaq Stock Market LLC indicating that the Company's common stock was subject to potential delisting from NASDAQ because, for a period of thirty (30) consecutive business days, the bid price of the common stock had closed below the minimum $1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 5550(a)(2) (the "Bid Price Rule"). The notification had no immediate effect on the listing or trading of the common stock on NASDAQ.

NASDAQ stated in its Letter that in accordance with the Nasdaq Listing Rules the Company was provided an initial period of 180 calendar days, or until November 6, 2019, to regain compliance. The Letter stated that the NASDAQ staff will provide written notification that the Company has achieved compliance with the minimum bid price listing requirement if at any time before November 6, 2019, the bid price of the common stock closes at $1.00 per share or more for a minimum of ten (10) consecutive business days.

On November 7, 2019, the Company received a written notification from NASDAQ notifying the Company that it is not eligible for a second 180 calendar day period to regain compliance due to the fact the Company fails to comply with Nasdaq's Marketplace Rule 5550(b)(1) because the Company's stockholders' equity as of June 30, 2019 fell below the required minimum of $5,000,000.

NASDAQ indicated in its letter that the Company may appeal the staff's determination to a Nasdaq hearings panel pursuant to the procedures set forth in the Nasdaq Listing Rule 5800 Series before 4:00 p.m. Eastern Time on or prior to November 14, 2019. On November 13, 2019, the Company filed such appeal and requested the staff grant a hearing (the "Hearing") and stay any delisting or suspension action by the staff pending the issuance of the hearings panel's decision. On November 14, 2019, the Company received a written letter from the NASDAQ Hearings Panel indicating that the requested hearing will be held on December 12, 2019, at 9:00 a.m. Eastern Time at the offices of NASDAQ. On November 22, 2019, the Company submitted its plan of compliance with the NASDAQ Hearings Panel.

We have not regained compliance as of the date of this prospectus. On November 25, 2019, we amended our amended and restated certificate of incorporation, as amended, to effect a 1-for-24 reverse split of our authorized and outstanding and issued shares of our common stock. The primary purpose of the reverse stock split was to increase the per share trading price of our common stock in order to regain compliance with the Bid Price Rule and maintain eligibility of our common stock for listing on the NASDAQ. Although we expect that the reverse stock split will result in an increase in the market price of our common stock, the reverse stock split may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors detailed from time to time in the reports we file with the SEC. We believe effectuation of the reverse stock split and the pendency of this offering may be viewed favorably by the NASDAQ Hearings Panel and help us avoid delisting of our common stock from the NASDAQ; however, we can provide no assurances that the NASDAQ Hearings Panel will accept our plan of compliance. If the NASDAQ Hearings Panel does not accept our plan of compliance or if we fail to regain compliance during any subsequent compliance period granted by NASDAQ Hearings Panel, our common stock will be subject to delisting by NASDAQ, which could seriously decrease or eliminate the value of an investment in our common stock.

***Termination of Howard R. Yeaton as Chief Executive Officer and interim Chief Financial Officer***

On November 1, 2019, the Board of Directors of the Company provided Mr. Howard R. Yeaton with sixty (60) days' notice of its intent to terminate him from each of his officer positions as Chief Executive Officer and interim Chief Financial Officer of the Company, pursuant to the employment agreement between the Company and Mr. Howard R. Yeaton, dated October 5, 2018. It is the Board of Director's intention to negotiate an arrangement with Mr. Yeaton whereby he will continue to serve past such sixty (60) day period in the role of interim Chief Financial Officer. There is no assurance that the Company will be able to reach such an agreement with Mr. Yeaton. There were no disagreements between the Company and Mr. Yeaton on any matters relating to the Company's operations, policies or practices.

***Appointment of Christopher C. Schreiber as Executive Chairman of the Board of Directors***

On November 1, 2019, the Board of Directors appointed Christopher C. Schreiber, a current director of the Company, as Executive Chairman of the Board of Directors of the Company, effective immediately. Due to Mr. Schreiber's appointment as Executive Chairman of the Board of Directors, Mr. Schreiber is no longer "independent" within the meaning of the Nasdaq Stock Market Rules and under Rule 10A-3(b)(1)(i) of the Securities Exchange Act of 1934 and is no longer a "non-employee director" under Rule 16b-3 of the Securities Exchange Act of 1934. As such, on November 1, 2019, Mr. Schreiber resigned from the Company's Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. In order to fill the vacancy occasioned by the resignation of Mr. Schreiber as the Chairman of the Compensation Committee, Mr. Joshua Silverman, a current director and member of the Compensation Committee, was appointed as the Chairman of the Compensation Committee.

***Appointment of Robert C. Schroeder as a Director***

On November 1, 2019, the Board of Directors appointed Robert C. Schroeder as a director and as a member of the Company's Audit Committee, effective immediately.

For more information regarding Robert C. Schroeder, including his biography, please refer to the Company's Form 8-K filed with the SEC on November 1, 2019, which is incorporated by reference herein.

***Reverse Stock Split***

On November 15, 2019, the Board of Directors approved a reverse stock split of our authorized and issued and outstanding common stock at a ratio of 1-for-24 to be effective on Monday, November 25, 2019 at 8:00 a.m. Trading on our common stock on a post-reverse stock split basis began at market open on November 25, 2019 (the "Reverse Stock Split"). No fractional shares have been issued in the Reverse Stock Split and the remaining fractions were rounded up to the next whole share. On November 22, 2019, the Board of Directors approved an amendment to the amended and restated certificate of incorporation to reduce the number of authorized shares of common stock, prior to the Reverse Stock Split, at a ratio of 1-for-8. Giving effect to the reverse stock split and the reduction in the number of authorized shares of common stock, we have 2,604,167 authorized shares of common stock and 523,343 shares of common stock issued and outstanding.

In connection with the Reverse Stock Split, all shares of our common stock subject to all outstanding equity awards and the exercise price of any such award (if applicable) has been reduced by the 1-for-24 ratio. The number of shares remaining available for issuance under Akers Biosciences, Inc. Equity Incentive Plans have not been reduced by the 1-for-24 ratio.

Please see below selected financial data presenting selected share and per share data reflecting the effect of the 1 for 24 reverse stock split. We derived the selected financial data for the three and nine months ended September 30, 2018 and 2019 from our unaudited condensed consolidated interim financial statements and related notes incorporated by reference in this prospectus. We derived the selected financial data for the years ended December 31, 2017, and 2018 set forth below from our audited consolidated financial statements and related notes incorporated by reference in this prospectus. Our results for interim periods are not necessarily indicative of the results that may be expected for the entire year.

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Net Loss | $ (837,026) | $ (3,083,950) | $ (2,548,875) | $ (7,011,394) |
| Basic and Diluted loss per common share | $ (1.61) | $ (6.28) | $ (4.89) | $ (15.57) |
| Weighted average basic and diluted common shares outstanding | 521,363 | 490,816 | 520,794 | 450,215 |

| | For the Years Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Net Loss | $ (10,849,034) | $ (7,366,310) |
| Basic and Diluted loss per common share | $ (23.73) | $ (150.88) |
| Weighted average basic and diluted common shares outstanding | 457,243 | 48,821 |

| | The Offering |
|---|---|
| **Class A Units offered by us in this offering:** | We are offering 613,500 Class A Units. Each Class A Unit consists of one share of our common stock and one warrant to purchase one share of our Series C Preferred Stock. The Class A Units will not be certificated and the shares of common stock and warrants comprising of such unit are immediately separable and will be issued separately in this offering.<br><br>This prospectus also relates to the offering of shares of our Series C Preferred Stock issuable upon the exercise of the investor warrants included in the Class A Units. |
| **Class B Units offered by us in this offering:** | We are also offering 1,376,500 Class B Units to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, in lieu of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering. Each Class B Unit consists of one pre-funded warrant to purchase one share of our common stock and one warrant to purchase one share of our Series C Preferred Stock. The purchase price for each Class B Unit is equal the per unit public offering price for the Class A Units in this offering less the $0.0001 per share exercise price of the pre-funded warrant included in the Class B Unit, and the exercise price of each pre-funded warrant is $0.0001 per share.<br><br>The Class B Units will not be certificated and the pre-funded warrants and warrants included in such unit are immediately separable and will be issued separately in this offering.<br><br>This prospectus also relates to the offering of shares of our common stock issuable upon exercise of the pre-funded warrants included in the Class B Units and the shares of our Series C Preferred Stock issuable upon the exercise of the investor warrants included in the Class B Units. |

| | |
|---|---|
| **Investor Warrants:** | Each investor warrant (other than the pre-funded warrants) included in the Units will have an exercise price equal to $4.00 per share of Series C Preferred Stock, will be exercisable upon issuance, and will expire five (5) years from the Charter Amendment Date. |
| **Series C Preferred Stock:** | This prospectus also relates to the offering of 1,990,000 shares of Series C Preferred Stock issuable upon the exercise of the investor warrants. Because there are insufficient number of authorized shares of common stock to cover the conversion of the shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock, the Series C Preferred Stock will not be convertible until the next business day after the Charter Amendment Date. Each share of the Series C Preferred Stock is convertible into one share of common stock. Notwithstanding the foregoing, we shall not effect any conversion of the Series C Preferred Stock, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series C Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% of the shares of common stock then outstanding after giving effect to such exercise. In the event our stockholders do not approve the Charter Amendment, the Series C Preferred Stock will not be convertible into common stock and the value of the warrants and the Series C Preferred Stock will be negatively affected. For additional information, see the subsection entitled "Description of Securities We Are Offering —Series C Convertible Preferred Stock" in this prospectus. |
| **Common stock to be outstanding after this offering:** | 2,513,343 shares of common stock (assuming full exercise of the pre-funded warrants included in the Class B Units sold in this offering) (1) (2) (3). |
| **Use of proceeds:** | We intend to use the net proceeds from this offering, together with our existing cash, for working capital and other general corporate purposes. See "Use of Proceeds." |
| **Dividend policy:** | We have never paid any cash dividends on our common stock, and we do not anticipate that we will pay any dividends with respect to those securities in the foreseeable future. Our current business plan is to retain any future earnings to finance the expansion and development of our business. See the section titled "Dividend Policy" for a more complete description of our dividend policy. |
| **Risk factors:** | An investment in our securities involves a high degree of risk. You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities. |
| **Market and Trading Symbol:** | Our shares of common stock are traded on the NASDAQ Capital Market under the symbol "AKER".<br><br>The Units will not be certificated and the securities included in such units are immediately separable and will be issued separately in this offering. There is no established trading market for the pre-funded warrants, investor warrants or Series C Preferred Stock, and we do not expect a trading market to develop. We do not intend to list the pre-funded warrants, investor warrants or Series C Preferred Stock on any securities exchange or other trading market. Without a trading market, the liquidity of the pre-funded warrants, investor warrants and Series C Preferred Stock will be extremely limited. |
| **Reverse Stock Split** | On November 15, 2019, the Board of Directors approved the reverse stock split to be effective on Monday, November 25, 2019 at 8:00 a.m. Trading of our common stock on a post-reverse stock split basis began at market open on November 25, 2019. No fractional shares were issued in the Reverse Stock Split and any remaining fraction were rounded up to the next whole share.<br><br>In connection with the Reverse Stock Split, all shares of our common stock subject to all outstanding equity awards and the exercise price of any such award (if applicable) has been reduced by the 1-for-24 ratio. The number of shares remaining available for issuance under the 2018 Akers Biosciences, Inc. Equity Incentive Plan will not be reduced by the 1-for-24 ratio. |

(1) The number of shares of common stock to be outstanding after this offering is based on 523,343 shares of common stock outstanding at December 4, 2019, after giving effect to the Reverse Stock Split and excludes the following:

- As of December 4, 2019, 87,947 shares of common stock issuable upon exercise of warrants outstanding at a weighted-average exercise price of $74.40 per share;
- As of December 4, 2019, 39 shares of common stock issuable upon exercise of options at a weighted-average exercise price of $236.16 per share;
- As of December 4, 2019, 15,603 shares of common stock are issuable upon the vesting of RSUs; and
- As of December 4, 2019, 1,859,397 shares of common stock are available for future issuances pursuant to the Akers Biosciences, Inc. 2018 Equity Incentive Plan, 3,967 shares of common stock available for future issuances pursuant to the Akers Biosciences, Inc. 2017 Stock Incentive Plan, and 1,470 shares of common stock available for future issuances pursuant to the Akers Biosciences, Inc. 2013 Stock Incentive Plan;

(2) Excludes the shares of common stock issuable upon conversion of the Series C Preferred Stock that is issuable upon exercise of the investor warrants to be issued in this offering.

(3) Also excludes 159,200 shares of common stock issuable upon exercise of warrants to be issued to the placement agent in this offering at an exercise price of 125% of the per unit public offering price for the Class A Units.

Unless otherwise indicated, all information in this prospectus reflects or assumes (i) no exercise of the placement agent's warrants to be issued to the placement agent in connection with this offering, and (ii) no exercise of the investor warrants or pre-funded warrants included in the Units sold in this offering.

## 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 risks described below, together with other information in this prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. The occurrence of any of the following risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.*

**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 nine months ended September 30, 2019 and 2018 were $2,548,875 and $7.011,394, respectively. Our accumulated deficit at December 31, 2018 was $115,694,881. Our strategy for the medical device business is to leverage where possible its distributor relationships, while exploring strategies for further reducing its costs. Overall, we are working to reduce our cash burn in order to have sufficient cash funds available to execute on a transaction which would result from our pursuit of strategic alternatives. There can be no assurance of success in reducing our loss, becoming profitable, or having sufficient cash to complete a strategic alternative transaction.

***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.***

As of September 30, 2019, we had two principal U.S. customers; Cardinal Health, Inc. (“Cardinal Health”) and Fisher Healthcare (“Fisher”) each has the non-exclusive right to distribute PIFA Heparin/PF4 Rapid Assays within the U.S. For the nine months ended September 30, 2019, Cardinal Health and Fisher accounted for approximately 81% of the Company’s product revenue.

Because of our dependence on a limited number of key customers, the loss of a major customer (or loss of a key program with a major customer), or any significant reduction in orders by a major customer or termination of the any of their distribution agreements would materially affect our business, our results of operations and our financial condition. We expect that sales to relatively few customers will continue to account for a significant percentage of our net sales for the foreseeable future, however there can be no assurance that any of these customers or any of our other customers will continue to utilize our products or our services at current levels.

***Due to our dependence on a limited number of customers, we are subject to a concentration of credit risk.***

As of September 30, 2019, three customers accounted for 97% of our trade receivables as compared to December 31, 2018, where 73% of trade receivables are attributed to these customers. One of these accounts, representing 66% of the gross trade receivables, was fully reserved as of September 30, 2019, and on September 21, 2019, this customer filed suit against the Company. In the case of insolvency by one of our significant customers, a trade receivable with respect to that customer might not be collectible, might not be fully collectible, or might be collectible over longer than normal terms, each of which could adversely affect our financial position.

***The Company’s business would suffer if the Company were unable to acquire adequate sources of supply.***

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements and disruption of these sources could have, at a minimum, a temporary adverse effect on shipments and the financial results of the Company. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. Any prolonged inability to obtain certain materials or components could have an adverse effect on the Company’s financial condition or results of operations and could result in damage to its relationships with its customers and, accordingly, adversely affect the Company’s business.

During the first half of 2018, we experienced lower yields in the process of extracting antigen from the supplier provided platelets used to produce our PIFA Heparin product. At these yield levels, our production of this product was under target levels, which had resulted in backorders.

***We will require additional capital in the future to support our operations or to pursue strategic alternative transactions. If we do not obtain any such additional financing, our business prospects, financial condition and results of operations will be adversely affected.***

We expect cash flows from our current operations to be inadequate to cover our anticipated expenses and we believe that our existing capital resources will only be sufficient to fund our current operations for the next ten to twelve months. As such, we will need to obtain significant additional financing, both in the short and long-term to cover operating expenses and to fund potential acquisitions. We may not be able to secure adequate additional financing when needed on acceptable terms, or at all. To execute our business strategy, we may issue additional equity securities in public or private offerings. If we cannot secure sufficient additional funding on a timely basis, we may be forced to forego strategic opportunities, delay, scale back or eliminate future product development, and/or be forced to sell assets, perhaps on unfavorable terms, which would harm our business and our ability to generate positive cash flows from operations needed to stay in business in the future, and ultimately could be forced to discontinue our operations and liquidate, in which event it is unlikely that stockholders would receive any distribution on their shares.

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.

***Because we may not be able to maintain or obtain 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.***

All of our existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products and may not be able to maintain the necessary regulatory clearances for some of our products.

The process of obtaining required approvals or clearances for a potential new product varies according to the nature of and uses for a specific product. These processes can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for the product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may be required to abandon a proposed product after devoting substantial time and resources to its development.

Changes in domestic and foreign government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

***We are subject to ongoing regulation by various government agencies, and, if we are unable to comply with such regulations, our products could be subject to restrictions or withdrawal from the market and/or we could be subject to a wide-range of enforcement actions, any of which would materially affect our business.***

In the United States, medical devices, including *in vitro* diagnostics, are subject to extensive regulation by FDA under the Federal Food, Drug, and Cosmetic ("FD&C") Act and its implementing regulations, along with other federal and state statutes and regulations. To be lawfully marketed in the United States, medical devices must generally receive 510(k) clearance or premarket approval ("PMA") from the FDA. All of our currently commercial devices have received 510(k) clearance.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include: compliance with the Quality System Regulation ("QSR"), which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; the reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk of health posed by the device or to remedy a violation of the FD&C Act; and the Medical Device Reporting ("MDR") regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur. Manufacturers are also required to register and list their devices with the FDA, based on which the FDA will conduct inspections to ensure continued compliance with applicable regulatory requirements.

The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters; fines; injunctions; consent decrees; civil penalties; repairs, replacements or refunds; recalls, corrections or seizures of products; total or partial suspension of production; the FDA's refusal to grant future premarket clearances or approvals; withdrawals or suspensions of current product applications; and criminal prosecution. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some people with brain related disorders from using our products and adversely affect our reputation and the perceived accuracy and safety of our products. If any of these events were to occur, they could have a material adverse effect on our business, financial condition and results of operations.

Additionally, as a U.S. medical device manufacturer, we must operate our production facility in accordance with the QSR requirements established by the FDA under the FD&C Act. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and recordkeeping. As such, we have implemented a quality system that is intended to comply with applicable regulations. Our manufacturing plant is subject to periodic inspections by the FDA, and at last inspection, the facility was found to be in substantial compliance with current good manufacturing practice (cGMP) requirements. Although the Company is dedicated to remaining in compliance with such practices, the cGMP requirements could change and negatively impact our ability to manufacture our products without modifications to our operating procedures or changes to our equipment or human resource allocations which may materially affect our business. If the FDA believes that our manufacturing practices are not compliant with applicable QSR requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

***If we fail to obtain regulatory approval in foreign jurisdictions, then we cannot market our products 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 current 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 may be unable to market our products outside the United States if our products cannot meet certain requirements of the Federal Food, Drug and Cosmetic Act requirements for exporting medical devices.***

Any medical device that is legally marketed in the U.S. may be exported anywhere in the world without prior FDA notification or approval. Medical devices that are not FDA-cleared for marketing legally in the U.S. may be exported under section 801(e)(1) of the FD&C Act, provided that they are intended for export only, they are class I or class II devices, and they are:

- In accordance with the specifications of the foreign purchaser;
- Not in conflict with the laws of the country to which they are intended for export;
- Labeled on the outside of the shipping package that they are intended for export; and
- Not sold or distributed in the U.S.

We cannot guarantee that certain current and future products will meet all of the aforementioned specifications for export which could adversely impact our ability to market our products outside the U.S.

***Modifications to our devices may require additional FDA clearance or approval, which could force us to cease marketing and/or recall the modified device until we obtain new approvals.***

After a device receives a 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a Premarket approval ("PMA"). The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and/or recall the modified devices until 510(k) clearance or PMA approval is obtained, among other enforcement actions. We have modified one of our prescription use, 510(k)-cleared devices, specifically the PIFA Heparin/PF4 Rapid Assay, to include our seraSTAT device. However, we determined that, in our view, based on FDA guidance as to when to submit a 510(k) notification for changes to a cleared device, a new 510(k) clearance was not required. We cannot assure you that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA approval. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval, which could harm our operating results and require us to redesign the product.

***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.

The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. 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.

***Our marketed products may be used by physicians for indications that are not cleared by the FDA. If the FDA finds that we promoted one or more of our products for off-label use(s), we may be subject to civil or criminal penalties.***

Under the FD&C Act and other laws, we are prohibited from promoting our products for "off-label" uses. This means that we may not make claims about the use of any of our marketed medical device products outside of their cleared indications, and that our website, advertising promotional materials and training methods may not promote or encourage any unapproved uses. Therefore, we may not provide information to physicians or patients that promote off-label uses, except in limited circumstances. Should the FDA determine that we have engaged in the promotion of any of our device products for off-label uses, the FDA could bring a wide range of enforcement actions against us and/or our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve or clear products, the withdrawal of an approved product from the market, product recalls, fines, disgorgement of profits, operating restrictions, injunctions or criminal prosecutions. Any of these adverse regulatory actions could result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business.

In addition to potential FDA enforcement, the Department of Justice, as well as state attorneys general, may work with the FDA or on their own to bring enforcement action against us and/or our executives in connection with any off-label promotion of our products. Such action may include civil and criminal penalties, including significant fines, among other serious consequences. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition, and ability to finance our operations. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

***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. The Company has not had the resources to effectively implement such clinical programs within its 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.

***If we fail to establish, maintain and expand relationships with distributors, sales of our products would decline.***

The Company does not control the efforts of its distributors and its distributors are not prohibited from selling competing products. Our ability to sell our products depends largely on the Company's relationships with such distributors. Accordingly, we are subject to the risk that they may not commit the financial and other resources to market and sell our products to our level of expectation, they may experience financial hardship or they may otherwise terminate our relationship on short notice. In the U.S. clinical laboratory marketplace, many of our existing and potential customers purchase our products through our two national distributors, Cardinal Health and Fisher Health. In addition, the Company relies on its distribution network to negotiate pricing arrangements and contracts with Group Purchasing Organizations and their affiliated hospitals and other members. For the nine months ended September 30, 2019, two customers generated 47% and 34%, or 81% in the aggregate, of the Company's revenue. For the nine months ended September 30, 2018, two customers generated 55%, and 17%, or 72% in the aggregate, of the Company's revenue. In the future, if we are unable to maintain existing relationships, our competitive position would likely suffer and our business would be harmed.

***Our business is vulnerable to the availability of raw materials, our ability to forecast customer demand and our ability to manage production capacity.***

Our ability to meet customer demand depends, in part, on our production capacity and on obtaining supplies, a number of which can only be obtained from a single supplier or a limited number of suppliers. A reduction or disruption in our production capacity or our supplies could delay products and fulfillment of orders and otherwise negatively impact our business.

We must accurately predict both the demand for our products and the lead times required to obtain the necessary components and materials. If we overestimate demand, we may experience underutilized capacity and excess inventory levels. If we underestimate demand, we may miss delivery deadlines and sales opportunities and incur additional costs for labor overtime, equipment overuse and logistical complexities. Additionally, our production capacity could be affected by manufacturing problems. Difficulties in the production process could reduce yields or interrupt production, and, as a result, we may not be able to deliver products on time or in a cost-effective, competitive manner. Our failure to adequately manage our capacity could have a material adverse effect on our business, financial condition and results of operations.

Our ability to meet customer demand also depends on our ability to obtain timely and adequate delivery of materials, parts and components from our suppliers. We generally do not maintain contracts with any of our key suppliers. From time to time, suppliers may extend lead times, limit the amounts supplied to us or increase prices due to capacity constraints or other factors. Supply disruptions may also occur due to shortages in critical materials. In addition, a number of our raw materials are obtained from a single supplier. Many of our suppliers must undertake a time-consuming qualification process before we can incorporate their raw materials into our production process. If we are unable to obtain materials from a qualified supplier, it can take up to a year to qualify a new supplier, assuming an alternative source of supply is available. A reduction or interruption in supplies or a significant increase in the price of one or more supplies could have a material adverse effect on our business, financial condition and results of operations.

***Some of our finished goods, including our PIFA products and control materials related to PIFA Heparin/PF4 assays, are temperature-sensitive.***

Proper packaging and time in transit are critical to the stability of some of our clinical laboratory products when they are en route to our distributors or end users. If certain specialized packaging materials cannot be obtained, and/or if our contracted common carriers, or those of our distributors, cannot meet product-specific delivery requirements, our products may not perform as intended and may lead to requests for product replacement. If such issues become widespread it could hurt our reputation and we could potentially lose customers which would adversely affect our business.

Also, given the issue of temperature sensitivity, time in transit may limit our ability to service potential markets outside of the U.S. for those products, especially those with geographies that do not allow for shipment and customs clearance within four business days. This could adversely affect our potential to generate revenue for some products on an international level.

***Demands of third-party payors, cost reduction pressures among our customers and restrictive reimbursement practices may adversely affect our revenue.***

Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or Group Purchasing Organizations ("GPOs"), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our products, to negotiate reduced prices or other concessions or to delay payment. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers or lower pricing for our products to new customers could have a material adverse effect on the financial position, cash flows and results of operations.

***Failure to obtain medical reimbursement for our products, as well as a changing regulatory and reimbursement environment, may impact our business.***

The U.S. healthcare regulatory environment may change in a way that restricts our ability to market our products due to medical coverage or reimbursement limits. Sales of our diagnostic tests will depend in part on the extent to which the costs of such tests are covered by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health payor administration authorities, private health coverage insurers and other third-party payors. These healthcare payors are increasingly challenging the prices charged for medical products and services. The containment of healthcare costs has become a priority of federal and state governments. Accordingly, our products may not be considered to be cost effective, and reimbursement may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products may change at any time and in ways that are difficult to predict and these changes may have an adverse effect to us.

CMS, the federal agency responsible for administering the Medicare program, along with its contractors establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products will be obtained or that such reimbursement will be adequate.

***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 the Company's 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 its 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. In September 2011, the U.S. Congress passed the Leahy-Smith America Invents Act ("AIA") which became effective in March 2013. The AIA reforms United States patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. It is difficult to predict the effect or impact the AIA will have on the operation of our business and the protection and enforcement of our intellectual property. While we believe that the AIA's post-grant review system is less expensive than litigation should we need to challenge a third party patent or defend our own patent, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries. We cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology (pre-AIA) or first to file (post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology similar or the same as ours. Any such patent application may have priority over our patent application and could further require us to obtain rights to such technologies in order to carry on our business. If another party has filed a U.S. patent application on inventions similar to or the same as ours, we may have to participate in an interference or other proceeding in the U.S. Patent and Trademark Office, or the USPTO, or a court to determine priority of invention in the United States, for pre-AIA applications and patents. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources.

***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 the Company has no knowledge of any claims against us, we may be subject to claims that these employees or the Company 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.

***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.

***The marketing, sale, and use of our PIFA products and any other devices we currently manufacture or may manufacture in the future 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.***

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic tests. We believe that our customers 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 impair our reputation and the public image of our tests and services, and we may be subject to legal claims arising from any defects or errors.

The marketing, sale, and 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 our marketing and promotional activities or as part of 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.

While our PIFA products are highly accurate, they 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. On July 25, 2019, we received a product-liability petition, alleging that multiple false-negative PIFA Heparin/PF4 Rapid Assay results caused a patient's treating hospital to delay the appropriate diagnosis by several days, which, the petition argues, was a substantial contributing factor in the ultimate amputation of the patient's left leg. We are contesting this action vigorously and believe our product liability insurance will be adequate to cover any costs incurred in connection with this matter. However, we cannot guarantee that our insurance will fully protect us from the financial impact of defending against product liability claims or any judgments, fines, or settlement costs arising out of any such claims.

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. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our services or cause our partners to terminate our agreements with them, any of which could adversely impact our results of operations.

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. For example, once brought to our attention, we reported the injury described above in connection with alleged false-negative PIFA Heparin/PF4 Rapid Assay results. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner 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 currently manufacture our products at a single location. Any disruption at this facility could adversely affect our business and results of operations.***

We currently manufacture all our products at our manufacturing plant. If our manufacturing plant were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace or rebuild the facility for the manufacture of our products. In such event, we would be forced to rely entirely on third-party contract manufacturers for an indefinite period of time. We do not currently have established relationships with any back-up manufacturers. Even if we are able to establish a relationship with a third-party manufacturer, there is no assurance that such manufacturer will be able to meet our needs from a technical, timing, or cost effective manner.

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

The Company is currently subject to a number of litigations, as discussed in the "Business" section. In connection with certain of these litigations, the Company has 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.

***We face substantial competition from other companies and our operating results may suffer if we fail to compete effectively.***

Competition among providers of rapid, point-of-care screening and testing products is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with many companies that have greater financial, product development, sales and marketing resources and experience than we do. Furthermore, new product development and technological change characterize the areas in which we compete. Our present or future products could be rendered obsolete or uneconomical as a result of technological advances by one or more of our present or future competitors. We must continue to develop and commercialize new products and technologies to remain competitive in the diagnostic testing industry. We believe that we compete primarily on the basis of our single-use testing. Customer and clinical support, and data that demonstrate both improvement in a patient's quality of life and a product's cost-effectiveness are additional aspects of competition.

We are aware of other rapid, point-of-care screening and diagnostic testing products in the U.S., Canada, and Europe. Specifically, Alere/Abbott, ACON Laboratories, Inc., Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation are companies that develop rapid, point-of-care screening and diagnostic testing products and currently maintain dominant market positions within the diagnostic testing market.

***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.***

We receive payments directly from or bill directly to Medicare, Medicaid or other national or third-party payers for our current product, U.S. federal and state healthcare laws and regulations pertaining to fraud or abuse are and 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 recent 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.

***Data security breaches may disrupt our operations and adversely affect our operating results.***

Our network security and data recovery measures and those of third parties with which we contract, may not be adequate to protect against computer viruses, cyber-attacks, breaches, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including patient data, could cause interruptions in our operations, could result in a material disruption of our business operations and could expose us to third-party legal claims. Furthermore, we could be required to make substantial expenditures of resources to remedy the cause of cyber-attacks or break-ins. This disruption could have a material adverse impact on our business, operating results and financial condition.

Our business processes personal medical information. The use of this information is critical to our operations and innovation. New and evolving regulations could bring increased scrutiny of our data management in the future. Any cyber-attacks or other failure to protect critical and sensitive systems and information could damage our reputation, prompt litigation or lead to regulatory sanctions, all of which could materially affect our financial condition and results of operation.

***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 are reviewing strategic alternatives and there can be no assurance that we will be successful in identifying or completing any strategic transaction, that any such strategic transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.***

In November 2018, we announced that our Board of Directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. We have not set a timetable for completion of this exploratory process and cannot provide any assurances that the process will result in the consummation of a strategic transaction of any kind, or that we will not abandon the process. We do not intend to discuss or disclose further developments during this process unless and until our board of directors has approved a specific action or we otherwise determine that further disclosure is appropriate. The process of reviewing strategic alternatives may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying, evaluating and negotiating potential strategic alternatives. We may not be able to successfully identify attractive acquisition candidates or negotiate favorable terms in the future. 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 or other strategic alternative, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. Until the review process is concluded, perceived uncertainties related to our future may result in the loss of potential business opportunities and volatility in the market price of our common stock and may make it more difficult for us to attract and retain qualified personnel and business partners.

***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.

***The Company, if it acquires a new business, or retains individuals with expertise in a new industry to pursue a strategic alternative, will have a limited operating history in such new industry, specifically the Cannabis industry, and may not succeed.***

The Company will have a limited operating history within the Cannabis industry and may not succeed. The Company will be subject to all risks inherent in a developing business enterprise. The Company's likelihood of continued success 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 the Company operates. For example, the Cannabis industry is a new industry that, as a whole, may not succeed, particularly if the Federal government changes course and decides to prosecute those dealing in Cannabis under Federal law. If that happens, there may not be an adequate market for the Company's products. As a new industry, there are not established players on whose business models the Company can follow or build upon. Similarly, there is limited information about comparable companies available for potential investors to review in making a decision about whether to invest in the Company. Furthermore, as the industrial hemp industry is a new market, it is ripe for technological advancements that could limit or eliminate the need for the Company's products. Furthermore, unanticipated expenses, problems, and technical difficulties may occur and they may result in material delays in the operation of the Company's business, in particular with respect to the Company's new products. The Company may not be able to successfully address these risks and uncertainties or successfully implement the Company's operating strategies. If the Company fails to do so, such failure could materially harm the Company's business to the point of having to cease operations and could impair the value of the Company's common stock to the point investors may lose their entire investment.

***If the Company acquires a business in the cannabis industry or otherwise pursues a strategic alternative, we would face additional unique and evolving risks.***

*Further legislative development beneficial to the cannabis industry is not guaranteed*

If the Company acquires a business in the cannabis industry or otherwise pursues a strategic alternative, the success of such business would depend on the continued development of the cannabis industry and the activity of commercial business and government regulatory agencies within the industry. The continued development of the cannabis industry is dependent upon continued legislative and regulatory authorization of cannabis at the state level and a continued laissez-faire approach by federal enforcement agencies. Any number of factors could slow or halt progress in this area. Further regulatory progress beneficial to the industry cannot be assured. While there may be ample public support for legislative action, numerous factors impact the legislative and regulatory process, including election results, scientific findings or general public events. Any one of these factors could slow or halt progressive legislation relating to cannabis and the current tolerance for the use of cannabis by consumers, which could adversely affect the business we may acquire or pursue. These changes may require us, should we acquire a business or otherwise pursues a strategic alternative in the cannabis industry, to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan. Furthermore, violations of these laws, or alleged violations, could disrupt our business and result in a material adverse effect on our operations. In addition, we cannot predict the nature of any future laws, regulations, interpretations or applications, and it is possible that regulations may be enacted in the future that will be directly applicable to the business we may acquire or pursue.

*The cannabis industry could face strong opposition from other industries*

We believe that established businesses in other industries may have a strong economic interest in opposing the development of the cannabis industry. Cannabis may be seen by companies in other industries as an attractive alternative to their products, including recreational marijuana as an alternative to alcohol, and medical marijuana as an alternative to various commercial pharmaceuticals. Many industries that could view the emerging cannabis industry as an economic threat are well established, with vast economic and federal and state lobbying resources. It is possible that companies within these industries could use their resources to attempt to slow or reverse legislation legalizing cannabis. Any inroads these companies make in halting or impeding legislative initiatives that would be beneficial to the cannabis industry could have a detrimental impact on our potential business.

*The legality of marijuana could be reversed in one or more states*

There is a substantial amount of change occurring in the U.S. regarding the use of medical and recreational marijuana products. While federal law prohibits the sale and distribution of cannabis products not approved or authorized by the FDA, at least 30 jurisdictions and the District of Columbia have enacted state laws to enable possession and use of marijuana in some form for medical purposes, and at least ten jurisdictions for recreational purposes. However, notwithstanding the permissive regulatory environment in some states, marijuana continues to be classified as a Schedule I controlled substance under the federal Controlled Substances Act and, thus, engaging in commercial activities involving such products violates federal law. Further, the voters or legislatures of states in which marijuana has already been legalized could potentially repeal applicable laws which permit the operation of both medical and retail marijuana businesses. These actions might force our potential business to cease operations in one or more states entirely.

*Banking regulations could limit access to banking services*

Since the use of marijuana is illegal under federal law, there is a compelling argument that banks cannot lawfully accept for deposit funds from businesses involved with marijuana. Consequently, businesses involved in the cannabis industry often have trouble finding a bank willing to accept their business. The inability to open bank accounts may make it difficult for our potential business to operate and our reliance on cash could result in a heightened risk of theft. Additionally, some courts have denied marijuana-related businesses bankruptcy protection, thus, making it very difficult for lenders to recoup their investments, which may limit the willingness of banks to lend to us.

*Insurance risks*

In the United States, many marijuana-related businesses are subject to a lack of adequate insurance coverage. In addition, many insurance companies may deny claims for any loss relating to marijuana or marijuana-related operations based on their illegality under federal law, noting that a contract for an illegal transaction is unenforceable. Thus, if we acquire a business or otherwise pursues a strategic alternative in the cannabis industry, we may have a difficult time obtaining certain insurances that are desired to operate our business, which may expose us to additional risks and financial liabilities.

**Risks Related to our Securities and the Offering**

***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.

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. On May 10, 2019, we received a notice from the staff (the "Staff") of NASDAQ that, for a period of thirty (30) consecutive business days, the bid price of our common stock had closed below the minimum $1.00 per share requirement for continued inclusion under NASDAQ Rule 5550(a)(2) (the "Bid Price Rule").

NASDAQ stated in its letter that in accordance with the NASDAQ Listing Rules we have been provided an initial period of 180 calendar days, or until November 6, 2019 to regain compliance.

On November 7, 2019, the Company received a written notification from NASDAQ notifying the Company that it is not eligible for a second 180 calendar day period to regain compliance due to the fact the Company fails to comply with Nasdaq's Marketplace Rule 5550(b)(1) because the Company's stockholders' equity as of June 30, 2019 fell below the required minimum of $5,000,000.

NASDAQ indicated in its letter that the Company may appeal the Staff's determination to a Nasdaq hearings panel pursuant to the procedures set forth in the Nasdaq Listing Rule 5800 Series before 4:00 p.m. Eastern Time on or prior to November 14, 2019. On November 13, 2019, the Company filed such appeal and requested the staff grant a hearing (the "Hearing") and stay any delisting or suspension action by the staff pending the issuance of the hearings panel's decision. On November 14, 2019, the Company received a written letter from the NASDAQ Hearings Panel indicating that the requested hearing will be held on December 12, 2019 at 9:00 a.m. Eastern Time at the offices of NASDAQ. On November 22, 2019, the Company submitted its plan of compliance with the NASDAQ Hearing Panel.

At the Hearing, we plan to present a plan of compliance to illustrate to the NASDAQ Hearings Panel our intentions to regain compliance with the listing requirements, including the recent implementation of the reverse stock split of our common stock. However, we can provide no assurances that the NASDAQ Hearings Panel will accept our plan of compliance and may determine to delist our common stock. Even if the NASDAQ Hearings Panel accepts our plan of compliance, we can provide no assurance that any action taken by us would be successful, or that any such action would stabilize the market price or improve the liquidity of our common stock. If we fail to continue to meet all applicable NASDAQ requirements, NASDAQ may determine to delist our common stock. If our common stock is delisted for any reason, it could reduce the value of our common stock and its liquidity.

If our common stock is delisted as a result of our failure to comply with the Bid Price Rule or any other NASDAQ continued listing requirement, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, delisting would substantially impair our ability to raise additional funds to fund our operations, to meaningfully advance the development of our products, and we could face other significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- a reduced amount of news and analyst coverage for us;
- reduced liquidity for our stockholders;
- potential loss of confidence by employees and potential future partners or collaborators; and
- loss of institutional investor interest and fewer business development opportunities.

***Our reverse stock split may not result in a proportional increase in the per share price of our common stock.***

We effected the reverse stock split of our common stock on November 25, 2019, with the primary intent of increasing the price of our common stock in order to regain compliance with the Bid Price Rule. The effect of the reverse stock split on the market price for our common stock cannot be accurately predicted. In particular, we cannot assure you that the proportionate increase in the prices of our common stock immediately after the reverse stock split from the prices for shares of our common stock immediately before the reverse stock split will be maintained for us to regain compliance with the Bid Price Rule or that the such market prices will be maintained for a substantial period of time. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. The market price of our common stock may also be affected by other factors which may be unrelated to the reverse stock split or the number of shares outstanding.

Moreover, because some investors may view the Reverse Stock Split negatively, we cannot assure you that the Reverse Stock Split will not adversely impact the market price of our common stock. Accordingly, our total market capitalization after the Reverse Stock Split may be lower than the market capitalization before the Reverse Stock Split.

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.***

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. 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. If we issue common stock or securities convertible or exercisable into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

***We will have broad discretion in how we use the net proceeds of this offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.***

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section entitled "Use of Proceeds." We intend to use the net proceeds from this offering for working capital and other general corporate purposes. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***An active trading market for our common stock may not be sustained.***

Although our common stock is listed on the NASDAQ, the market for our shares has demonstrated varying levels of trading activity. There has been limited trading of our common stock in the U.S since we began trading on NASDAQ in January 2014. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

***The reverse stock split may decrease the liquidity of the shares of our common stock.***

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that are outstanding following the reverse stock split. In addition, the reverse stock split increased the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

***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 of directors 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 of directors. 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.

***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.

***Non-U.S. investors may have difficulty effecting service of process against us or enforcing judgments against us in courts of non-U.S. jurisdictions.***

We are a company incorporated under the laws of the State of New Jersey. All of our directors and officers reside in the United States. It may not be possible for non-U.S. investors to effect service of process within their own jurisdictions upon our company and our directors and officers. In addition, it may not be possible for non-U.S. investors to collect from our company, its directors and officers, judgments obtained in courts in such non-U.S. jurisdictions predicated on non-U.S. legislation.

***Holders of the pre-funded warrants or investor warrants will not have rights of common stockholders until such pre-funded warrants or warrants are exercised (and in the case of the warrants, the shares of Series C Preferred Stock are converted into shares of common stock), subject to certain limited exceptions.***

Until holders of pre-funded warrants or investor warrants acquire shares of our common stock upon exercise of the pre-funded warrants or upon exercise of the investor warrants and conversion of the shares of Series C Preferred Stock underlying the investor warrants, holders of pre-funded warrants or investor warrants will have no rights with respect to the shares of our common stock underlying such securities. Upon exercise of the pre-funded warrants or exercise of the investor warrants and conversion of the Series C Preferred Stock underlying the investor warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise, subject to certain limited exceptions.

***There is no public market for the pre-funded warrants, investor warrants or Series C Preferred Stock being offered in this offering.***

There is no established public trading market for the pre-funded warrants, investor warrants or Series C Preferred Stock being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants, investor warrants or Series C Preferred Stock on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active trading market, the liquidity of the pre-funded warrants, investor warrants and Series C Preferred Stock will be limited.

***The investor warrants and the pre-funded warrants in this offering are speculative in nature.***

Except in limited circumstances, neither the warrants nor the pre-funded warrants in this offering confer any rights of common stock or Series C Preferred Stock ownership on its holders, such as voting rights, but rather merely represent the right to acquire shares of common stock or Series C Preferred Stock at a fixed price, as the case maybe, and, with respect to the investor warrants, during a fixed period of time. Specifically, commencing on the date of issuance, holders of the investor warrants may exercise their right to acquire Series C Preferred Stock and pay an exercise price of $4.00 per share of Series C Preferred Stock, subject to certain adjustments, prior to the expiration of the warrants.

Moreover, following this offering, the market value of the warrants and the pre-funded warrants, if any, is uncertain and there can be no assurance that the market value of the warrants or the pre-funded warrants will equal or exceed their imputed offering price. Neither the warrants nor the pre-funded warrants will be listed or quoted for trading on any market or exchange.

***There are insufficient number of authorized shares of common stock to cover the conversion of all outstanding shares of Series C Preferred Stock into common stock, and if we do not obtain shareholder approval to increase the number of our authorized shares of common stock in an amount sufficient to issue shares to those who purchase investor warrants in this offering, the warrants included in this offering may not have any value and you could lose part or all of your investment.***

We do not have a sufficient number of authorized shares of common stock to cover the shares issuable upon conversion of the Series C Preferred stock being offered by this prospectus. Because there are insufficient number of authorized shares of common stock to cover the conversion of the shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock, before the Series C Preferred Stock can become convertible, we will need to receive stockholder approval of the Charter Amendment (which is an amendment to our certificate of incorporation to sufficiently increase our authorized shares of common stock to cover the conversion of all shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock). We have agreed in the securities purchase agreement for this offering to use our reasonable best efforts to obtain such approval within 60 days from the date of this prospectus. We intend to seek stockholder approval to amend our amended and restated certificate of incorporation, as amended, to increase the number of authorized shares of common stock from 2,604,167 to 100,000,000 shares at our 2019 annual meeting of stockholders scheduled to be held on December 30, 2019. We cannot assure you that we will be able to obtain requisite stockholder approval of the Charter Amendment. In the event our stockholders do not approve the Charter Amendment, the Series C Preferred Stock will not be convertible into common stock and the value of the investor warrants and the Series C Preferred Stock will be negatively affected.

***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.

***The Series C Preferred Stock will rank junior to all our liabilities to third party creditors in the event of a bankruptcy, liquidation or winding up of our assets.***

In the event of bankruptcy, liquidation or winding up, our assets will be available to pay obligations on the Series C Preferred Stock only after all our liabilities have been paid. The Series C Preferred Stock will effectively rank junior to all existing and future liabilities held by third party creditors. The terms of the Series C Preferred Stock do not restrict our ability to raise additional capital in the future through the issuance of debt. In the event of bankruptcy, liquidation or winding up, there may not be sufficient assets remaining, after paying our liabilities, to pay amounts due on any or all of the Series C Preferred Stock then outstanding.

***Future issuances of preferred stock may adversely affect the market price for common stock.***

Upon the consummation of the offering, we will issue investor warrants exercisable into 1,990,000 shares of Series C Preferred Stock, which are convertible into an aggregate of 1,990,000 shares of common stock. These shares of common stock issuable upon conversion of the Series C Preferred Stock underlying investor warrants can be resold into the public market immediately without restriction, unless such shares are owned by our affiliates or subject to lock-up agreements. Additional issuances or sales of preferred stock, or the perception that such issuances or sales could occur, may cause prevailing market prices for common stock to decline and may adversely affect our ability to raise additional capital in the financial markets at times and prices favorable to us.

***We are an "emerging growth company" and may elect to comply with reduced public company reporting requirements, which could make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act. For as long as we continue to be an "emerging growth company", we may take advantage of exemptions from various reporting requirements that are applicable to other public reporting companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports. We expect to cease to be an "emerging growth company" on December 31, 2019, although circumstances could cause us to lose that status earlier if our annual revenues exceed $1.07 billion, if we issue more than $1.0 billion in non-convertible debt in any three-year period or if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30th, in which case we would no longer be an "emerging growth company" as of the following December 31st. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

***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 REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and documents incorporated by reference in this prospectus contain forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this prospectus and documents incorporated by reference in this prospectus. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements.

Examples of forward-looking statements in this prospectus and documents incorporated by reference in this prospectus include, but are not limited to, our expectations regarding our business strategy, business prospects, operating results, operating expenses, working capital, liquidity and capital expenditure requirements. Important assumptions relating to the forward-looking statements include, among others, assumptions regarding demand for our products and services, the cost, terms and availability of components, pricing levels, the timing and cost of capital expenditures, competitive conditions and general economic conditions. These statements are based on our management's expectations, beliefs and assumptions concerning future events affecting us, which in turn are based on currently available information. These assumptions could prove inaccurate. Although we believe that the estimates and projections reflected in the forward-looking statements are reasonable, our expectations may prove to be incorrect.

Important factors that could cause actual results to differ materially from the results and events anticipated or implied by such forward-looking statements include, but are not limited to:

- changes in the market acceptance of our products and services;
- 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 the proprietary rights of the Company; and
- other risks, including those described in the "Risk Factors" discussion of this prospectus.

We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all of those risks, nor can we assess the impact of all of those risks on our business or the extent to which any factor may cause actual results to differ materially from those contained in any forward-looking statement. The forward-looking statements in this prospectus and in the documents incorporated by reference herein are based on assumptions management believes are reasonable. However, due to the uncertainties associated with forward-looking statements, you should not place undue reliance on any forward-looking statements. Further, forward-looking statements speak only as of the date they are made, and unless required by law, we expressly disclaim any obligation or undertaking to publicly update any of them in light of new information, future events, or otherwise.

## USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $7.0 million from the initial sale of the Units in this offering, assuming the full exercise of the pre-funded warrants sold in this offering and after deducting the placement agent fees and estimated offering expenses payable by us. If all of the investor warrants sold in this offering were to be exercised in cash at an exercise price of $4.00 per share of Series C Preferred Stock, we would receive additional net proceeds of approximately $7.96 million. However, the investor warrants contain a cashless exercise provision that permits exercise of the warrants on a cashless basis at any time when there is no effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, covering the issuance of the underlying shares of Series C Preferred Stock. We cannot predict when or if these investor warrants will be exercised. It is possible that these warrants may expire and may never be exercised.

Although we currently anticipate that we will use the net proceeds from the offering for working capital and other general corporate purposes, there may be circumstances where a reallocation of funds is necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including our sales and marketing and commercialization efforts, demand for our products, our operating costs and the other factors described under "Risk Factors" in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Although we may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, or for other strategic investments or opportunities, we have no current understandings, agreements or commitments to do so.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and do not expect to pay any cash dividends on our common stock for the foreseeable future. We intend to use future earnings, if any, in the operation and expansion of our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors, based on our financial condition, results of operations, contractual restrictions, capital requirements, business properties, restrictions imposed by applicable law and other factors our board of directors may deem relevant.

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

**Market Information**

Our common stock began trading on the NASDAQ Capital Market under the symbol "AKER" on January 23, 2014. Prior to that, our common stock traded on the OTCQB of the OTC Markets Group Inc. under the same symbol.

The last reported closing price for our common stock on the NASDAQ Capital Market on December 5, 2019, was $3.16 per share.

## CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2019:

- on an actual basis, giving effect to the Reverse Stock Split;
- on an as-adjusted basis to give effect to the Reverse Stock Split and the issuance and sale by us of 613,500 Class A Units and 1,376,500 Class B Units, assuming the full exercise of the pre-funded warrants included in the Class B Units sold in this offering, after deducting placement agent fees and estimated offering expenses payable by us.

You should read the information in this table together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes incorporated by reference into this prospectus.

| | As of September 30, 2019 | |
|---|---|---|
| | Actual | As Adjusted |
| | (unaudited) (in thousands, except per share data) | |
| Cash and cash equivalents | $ 363 | $ 7,350 |
| Other long-term liabilities | $ - | $ - |
| Stockholders' equity (deficit): | | |
| Preferred stock, no par value; 50,000,000 authorized, 0 issued and outstanding (actual), 0 issued and outstanding (as adjusted) | - | = |
| Common stock, no par value; 2,604,167 authorized, 521,520 issued and outstanding (actual); 2,511,520 issued and outstanding (as adjusted) | 121,822 | 128,809 |
| Accumulated Other Comprehensive Income | 20 | 20 |
| Accumulated Deficit | (118,244) | (118,244) |
| Total shareholders' equity | 3,598 | 10,585 |
| Total capitalization | $ 3,598 | $ 10,585 |

The number of shares of our common stock to be outstanding upon completion of this offering is based on 521,520 shares of our common stock outstanding as of September 30, 2019, after giving effect to the reverse stock split, assumes that there is no sale of any Class B Units in this offering and excludes:

- As of September 30, 2019, 87,947 shares of common stock issuable upon exercise of warrants outstanding at a weighted-average exercise price of $74.40 per share;
- As of September 30, 2019, 39 shares of common stock issuable upon exercise of options at a weighted-average exercise price of $236.16 per share;
- As of September 30, 2019, 15,603 shares of common stock issuable upon vesting of RSUs;
- 1,859,397 shares of common stock available for future issuances pursuant to the Akers Biosciences, Inc. 2018 Equity Incentive Plan, 3,967 shares of common stock available for future issuances pursuant to the Akers Biosciences, Inc. 2017 Stock Incentive Plan, and 1,470 shares of common stock available for future issuances pursuant to the Akers Biosciences, Inc. 2013 Stock Incentive Plan;
- 1,990,000 shares of common stock issuable upon conversion of the Series C Preferred Stock issuable upon exercise of the investor warrants to be issued in this offering; and
- 159,200 shares of common stock issuable upon the exercise of placement agents warrants.

## BUSINESS

*Medical Device Business*

On October 8, 2018, we announced that following a review of the Company's commercial and product development strategies, the Board of Directors has determined that it is in the best interests of the Company to focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform. PIFA® technology is a patented immunoassay method which rapidly and accurately detects target antigens or antibodies. It is the technology platform utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. These products account for the significant majority of the Company's current revenues.

Through June 30, 2019, we continued to manufacture BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC) Biosensor technology platform) and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform). In September 2019, we have determined that it is no longer economically appropriate to offer our Tri- Cholesterol product. Furthermore, we have determined that it is not economically appropriate to further develop or pursue approval of the PIFA PLUSS Chlamydia Rapid Assay device. As of September 30, 2019, the Company's marketed products consist only of its PIFA® Heparin/PF4, PIFA PLUSS® PF4 and BreathScan Alcohol Detectors.

All of our rapid, single-use tests are performed in vitro (outside the body) and are designed to enhance patient well-being and reduce the cost of healthcare. The Company's 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.

We believe that low-cost, single-use testing not only saves time and money, but allows for more frequent, near-patient testing which may save lives. We believe that our FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment. We also believe that our rapid diagnostic tests surpass most other current diagnostic products with their flexibility, speed, ease-of-use, readability and low cost.

We believe the use of rapid tests, which can be performed at the point-of-care when and where the patient is being consulted, can result in immediate diagnostic decisions and subsequent treatment regimens and is an important development in the practice of medicine. Point-of-care testing addresses today's challenges in the healthcare industry, such as:

- cost pressures/efficiency of healthcare delivery; and
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness

*Strategy*

Our strategy for the medical device business is to leverage where possible its distributor relationships, while exploring strategies for further reducing its costs.

We have developed and currently maintain strategic relationships with established companies that are in the clinical laboratory market.

*Current Testing Platform Technologies*

**Particle ImmunoFiltration Assay (PIFA®) Technology**

PIFA ® technology is an accurate, rapid, immunoassay (*a procedure for detecting or measuring specific proteins or other substances through their properties as antigens or antibodies*) method based on the selective filtration of dyed microparticles coated with antigen or antibody. The microparticles are combined with a test sample (whole blood or serum) within a self-contained device. If a patient tests positive for the antibody or antigen, a binding event will occur and the dyed microparticles will be trapped by a filter within the device. As a result, the test window will be void of any color. Conversely, if the patient tests negative, the dyed microparticles will flow freely into the test window. Specific to the PIFA Heparin tests, the Company has two international patents and one US patent granted in force.

**MPC Biosensor Technology**

MicroParticle Catalyzed Biosensor ("MPC Biosensor") Technology permits the rapid identification of medical conditions through biomarkers in exhaled breath. MPC Biosensor-based products contain microparticles that change color to indicate a positive test result. The microparticles are coated with agents that both decrease the time to result and exhibit a more defined color change when appropriate. MPC Biosensor-based products are packaged in small, disposable cartridges through which test subjects can easily blow for several seconds.

*Current Sample Preparation Technology*

**Rapid Blood Cell Separation Technology**

Our Rapid Blood Cell Separation ("Separator") Technology, labeled under the brand name seraSTAT ®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment. The disposable Separator device requires only a small-volume blood sample obtained through a venous blood draw. We have obtained the appropriate US FDA regulatory clearances for seraSTAT ® as a stand-alone device and the technology is currently integrated into PIFA PLUSS PF4 devices. The seraSTAT ® Rapid Blood Cell Separation Technology is currently protected by two U.S. patents and three international patents.

*Current Product Portfolio*

We are positioned as a provider of rapid diagnostic solutions.

At present, our commercialized product portfolio incorporates the three aforementioned proprietary platform testing and sample preparation technologies: PIFA®, MPC Biosensor and Rapid Blood Cell Separation Technology.

The following table sets forth our marketed products, identifies the appropriate "prescription use" or "OTC" designation and the required clearance that has been obtained.

Our marketed and emerging products include:

| Product | Platform | Marketed/Pipeline | FDA Clearance Required Prescription Use/OTC | FDA Clearance Status Obtained/Needed | Description |
|---|---|---|---|---|---|
| BreathScan ™ | MPC | Marketed | OTC | Obtained | Disposable breath alcohol detector |
| PIFA ® Heparin/PF4 & PIFA PLUSS ® PF4 | PIFA | Marketed | Prescription Use | Obtained | Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin |
| seraSTAT ® | seraSTAT | Marketed | Prescription Use | Obtained | Rapid Blood Cell Separator, marketed under the brand name seraSTAT ®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. |

*PIFA ® Technology*

The core products marketed under the PIFA ® platform are the PIFA ® Heparin/PF4 Rapid Assay, and the PIFA PLUSS ® PF4.

PIFA ® Heparin/PF4 Rapid Assay and PIFA PLUSS ® PF4 remain the only FDA-cleared rapid manual assays we are aware of that can quickly determine if a patient being treated with the blood thinner Heparin may be developing a drug allergy. This clinical syndrome, referred to as Heparin-Induced Thrombocytopenia ("HIT"), reverses the Heparin's intended therapeutic effect and transforms it into a clotting agent. Patients with HIT are at risk of developing limb- and life-threatening complications, so the timely test result provided by our Heparin/PF4 devices is paramount to effective clinical decision making. The largest at-risk populations are patients undergoing major cardiac or orthopedic surgical procedures. Given the size of the aging baby boomer market segment and the prevalence of cardiac disease, surgeries within this category are expected to increase, as would the potential demand for the Company's convenient, rapid tests.

We believe the PIFA ® Heparin/PF4 Rapid Assay improves the standard of care in HIT-testing by delivering results in less than five minutes after the patient sample has been prepared. Traditional methods required the use of expensive equipment, specialized laboratory personnel and hours of technician time to complete the 20+ assay test procedure in-house. Clinicians were subjected to a 24-to-72 hour turnaround time if the HIT-antibody determination was outsourced to a reference laboratory. Especially in the latter scenario, the patient information obtained is retrospective in nature as the HIT-antibody result cannot be factored into time-sensitive diagnostic and treatment decisions.

The Company has also introduced PIFA PLUSS ® PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result. This PIFA ® line extension merges the ease-of-use of the PIFA testing platform with our recently patented Rapid Blood Cell Separation Technology, marketed under the brand name seraSTAT ®. The marriage of these two technologies condenses the sample preparation and analysis procedures as the precise micro-volume of a seraSTAT® -prepared patient specimen is delivered directly into the PIFA ® cassette for immediate testing. This eliminates an additional one-hour of sample processing time and the need for healthcare personnel to have access to a centrifuge to separate the liquid fraction of blood from the cellular fraction. As a result, HIT-testing can be initiated and completed at or near the point-of-care, especially in emergency and critical care departments where time-efficient diagnostic results can drastically improve patient outcomes.

Since we believe the appropriate regulatory clearances have been obtained in the United States for these products, we do not plan to fund additional clinical trials to facilitate product marketing domestically. In addition, the current technical file that has been assembled for seraSTAT ® and PIFA PLUSS PF4 ® also is expected to be used to support our CE-marking self-certification process for potential sales in the EU; the PIFA Heparin/PF4 Rapid Assay is already CE-marked.

*MPC Biosensor Technology*

Breath Alcohol Products

BreathScan® is a single use disposable breath alcohol detector and has 510(k) clearance for Over-the-Counter sales to U.S. consumers; CE certification is not required to market the product in the EU because BreathScan ® results are not used to diagnose any medical conditions.

The Company's disposable breath alcohol detectors are available in versions designed to detect .02%, .04%, .05% and .08% blood alcohol concentrations ("BACs") and provide users with a test result in two minutes. If the crystals in the interior of the device change from yellow to aqua, the user has tested positive for the specific alcohol level. Should the crystals remain yellow, the result is negative.

*Sample Preparation Technology*

Rapid Blood Cell Separation Technology

In addition to the Company's testing platforms, our patented Rapid Blood Cell Separation ("Separator") Technology, marketed under the brand name seraSTAT ®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment.

The required micro-volume specimen of serum or plasma is immediately extracted and introduced into a rapid assay device for real-time analysis. The savings afforded by the Separator device can be measured in time and cost given its quick turn-around-time and straightforward, easy-to-master procedure.

Currently, seraSTAT ® is integrated into PIFA PLUSS PF4 devices. We have modified one of our prescription use, 510(k)-cleared devices, specifically the PIFA Heparin/PF4 Rapid Assay to include our seraSTAT device. However, we determined that, in our view, based on FDA guidance as to when to submit a 510(k) notification for changes to a cleared device, new 510(k) clearances or PMA approvals were not required. We cannot assure you that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA approval. The seraSTAT ® Rapid Blood Cell Separation Technologies is currently protected by two United States patents (7,896,167; 8,097,171) and one international patent (JP 4,885,134).

*Competition*

Competitors of ours include other companies developing and marketing rapid, point-of-care diagnostic devices and companies with dedicated laboratory instruments and/or automated test systems. We face intense competition from companies with dominant market positions within the *in vitro* diagnostic testing market such as Alere/Abbott, ACON Laboratories, Inc., Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation.

The Company believes the primary criteria for determining competitiveness within the rapid point-of-care sector are cost, ease-of-use, speed, readability, accuracy and flexibility.

That said, our competitors have significantly greater financial, technical, marketing and other resources than we have and may be better able to:

- respond to new technologies or technical standards;
- devote resources to the development, production, promotion, support and sale of products;
- acquire other companies to gain new technologies or products that may displace our product lines;
- react to changing customer requirements and expectations;
- manufacture, market and sell products; and
- deliver a broad range of competitive products at lower prices.

Our principal competitors are able to leverage their broader product portfolios and dominant market positions in some segments by, for example, bundling their products into specially priced packages that create strong financial incentives for their customers to purchase their products. These practices may negate savings customers would gain from buying select products from us and may deter such customers from buying our products. We expect competition in the markets in which we participate to continue to increase as existing competitors improve or expand their product offerings.

*How we Generate Revenue*

Our revenue comes from selling rapid, screening and testing products, largely through our distributor networks. Most of our assays are used in the clinical laboratory to ultimately help healthcare professionals to diagnose a medical condition or complication that may require treatment. Other products can be sold over-the-counter, to the general public, to help assess an individual's status as it relates to his/her blood alcohol or cholesterol level.

*Our Current Markets*

Regarding the Company's test for the heparin drug allergy, the testing market largely resides within the clinical hospital laboratories of medical facilities.

The markets for alcohol breathalyzers are reached through a network of small distributors and director customers and principally serve industrial safety markets.

*Manufacturing and Suppliers*

We are a vertically integrated manufacturer, producing substantially all of our devices in-house. The vast majority of our products start out as high quality, medical grade polymers and exit our facilities as fully manufactured and packaged medical devices. As a result, we have a short supply line between our raw materials and finished goods which gives us greater control over our product quality. The downside of our in-house manufacturing is the requirements for facilities, personnel, and equipment. This approach also requires mid-to-long-term planning and the ability to predict future needs. Many of our processes are unique to us, but the Company's flexible manufacturing capabilities and unused current capacity generally translate into relatively short production timelines.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements. U.S. medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices ("cGMP's"). cGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements.

Effective February 2, 2018, the Company's quality management system was certified as compliant with the International Standards Organization's ("ISO") 13485:2016 requirements for the design, manufacture and distribution of medical devices including in vitro diagnostic products.

*Distribution*

We distribute our products through direct and indirect channels of distribution. We have indirect distribution channels in the U.S. with, among others, Cardinal Health, Inc. ("Cardinal Health") and Fisher Healthcare, a Division of Thermo Fisher Scientific Inc. ("Fisher Healthcare") for the Company's PIFA Heparin/PF4 assays. The relationships with Cardinal Health and Fisher Healthcare provide us with access to most U.S. hospitals.

The Company's PIFA Heparin/PF4 assays are also sold direct to certain hospitals and buying groups.

With respect to the Company's breath alcohol product, we have focused our commercial attention within the on-the-job safety/human resources sector. Access was and currently is largely achieved through designated BreathScan ® distributors and limited arrangements in which the Company serves in an OEM capacity.

*Intellectual Property*

We rely on a combination of patent, trademark and trade secret laws in the U.S. and other jurisdictions to protect our proprietary platform technologies and our brands. We also rely on confidentiality procedures and agreements with key employees and distribution/business partners where appropriate, and contractual provisions to achieve the same. We do not pursue patent protection where the possibility for meaningful enforcement is limited.

Our logo is a registered trademark in the U.S. Other registered trademarks/service marks include: BreathScan®, PIFA ®, PIFA PLUSS ®, seraSTAT ®.

The following table summarizes the U.S. and international utility patents that currently protect our intellectual property for actually marketed products:

| Description | Jurisdiction | Utility Patent No. | Type of Protection | Expiration Date | Product(s) To Which They Relate |
|---|---|---|---|---|---|
| blood separator | US | 7,896,167 | Manufacture | 9/7/2026 | seraSTAT ® ; PIFA PLUSS ® PF4; PIFA PLUSS ® Rapid Assays |
| method of separating fluid fraction from whole blood | US | 8,097,171 | Process | 8/5/2025 | seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Rapid Assays |
| blood separator and method of separating fluid fraction from whole blood | Japan | 4,885,134 | Manufacture | 8/5/2025 | seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Rapid Assays |
| blood separator | European Union | 1793906 | Manufacture | 8/5/2025 | seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Rapid Assays |

| Description | Jurisdiction | Utility Patent No. | Type of Protection | Expiration Date | Product(s) To Which They Relate |
|---|---|---|---|---|---|
| blood separator | Hong Kong | 1104006 | Manufacture | 8/5/2025 | seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Infectious Diseases Rapid Assays |
| methods for detecting heparin/ platelet factor 4 antibodies | US | 9,383,368 | Process | 10/4/2024 | PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4 |
| methods and kits for detecting heparin/platelet factor 4 antibodies | Japan | 4,931,821 | Manufacture | 10/4/2025 | PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4 |
| Methods and kits for detecting heparin/ platelet factor 4 antibodies | Japan | 5775790 | Manufacture | 10/4/2025 | PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4 |

Circumstances outside our control could pose a threat to our intellectual property. For example, effective intellectual property protection may not be available in every country in which our products are distributed. Also, the efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights is costly and time consuming. Any increase in unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results.

The PIFA Heparin/PF4 Rapid Assay is CE-marked for sale in the EU for professional use. The CE-mark must be affixed to a product that is intended, by the manufacturer, to be used for a medical purpose.

*Foreign Regulation*

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 sale of some medical devices within the European Union. Some of our current products that require CE Markings have them and it is anticipated that additional and future products may require them as well. As of the date of this filing, the Company has received CE marks for its commercialized products/product components: PIFA Heparin/PF4 Rapid Assay and Heparin/PF4 Serum Panels.

*Third-Party Reimbursement*

Health care providers, including hospitals, that purchase our products generally rely on third-party payors, including the Medicare and Medicaid programs, and private payors, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payors.

CMS, the federal agency responsible for administering the Medicare program, along with its contractors establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

In general, Medicare will cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage. For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products, will be obtained or that such reimbursement will be adequate.

*Other U.S. Regulation*

We must also comply with numerous federal, state and local laws relating to matters such as healthcare fraud and abuse, anti-kickback, false claims, HIPAA, environmental protection, safe working conditions, manufacturing practices, fire hazard control and, among other things, the generation, handling, transportation and disposal of hazardous substances.

*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. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. On November 19, 2018, the Company further announced that in its evaluation of strategic alternatives it will consider a range of potential strategic alternatives including, but not limited to, business combinations in sectors different than that currently engaged in, including cannabis related industries. The Board of Directors may also pursue a strategic alternative in one of the aforementioned industries by retaining individuals that have expertise in those industries. On December 4, 2019, the Board of Directors of the Company formed an advisory board (the "Advisory Board") with expertise in the hemp and minor cannabinoid. The Company will continue its strategic alternatives review and has identified the hemp and minor cannabinoid sectors as potential opportunities that could benefit from Akers' core competencies. The Company is exploring how to leverage its 30 years of operational history in its medical device business, where its current products have U.S. Food and Drug Administration (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 Advisory Board will assist the Board of Directors in its strategic review including, potentially, the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry. The Advisory Board may also explore a pathway to consumer products with a focus on minor cannabinoids.

*Available information*

Our website address is *www.akersbio.com*. We do not intend our website address to be an active link or to otherwise incorporate by reference the contents of the website into this Report. The SEC maintains an Internet website (*http://www.sec.gov* ) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

**Employees**

We currently employ 11 full-time equivalent employees, contractors or consultants, which include four in general and administrative, three in regulatory compliance and six in direct and indirect manufacturing. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that we have good relations with our employees.

**Legal Proceedings**

*Pulse Health LLC v Akers Biosciences, Inc. No.: 3:16-cv-01919-HZ*

On October 10, 2016, the Company was served with a notice that Pulse Health LLC ("Pulse") filed a lawsuit against the Company on September 30, 2016 in United States Federal District Court, District of Oregon, alleging a breach of contract under the settlement agreement entered into by the Company and Pulse on April 8, 2011 which settled all claims and disputes between the Company and Pulse arising from a previously executed Technology Development Agreement entered into by the Company and Pulse and damages resulting from said alleged breach. Additionally, Pulse alleged false advertising and unlawful trade practices in connection with the Company's sales activities related to the Company's OxiChek™ products.

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of personal jurisdiction or, in the alternative, transfer of the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim on which relief could be granted. Oral arguments on these motions were heard by the Court on March 10, 2017.

The Court decided by order dated April 14, 2017 in favor of the Company and dismissed with prejudice the claims brought by Pulse for unfair competition (both federal and state counts). The court decided against the Company in its motions for transfer of venue and for lack of personal jurisdiction. As such, the case proceeded in the District Court of Oregon.

The Company filed a Motion for Summary Judgment on January 24, 2018. On June 21, 2018, the Court ruled in favor of the Company on one issue and determined that other issues warranted a trial. The Court further determined that equitable relief, such as an injunction, "may be warranted." Following such rulings, the Company discovered certain deficiencies in its discovery responses and took appropriate steps to supplement the record and correct these deficiencies.

On September 17, 2018, the Company and Pulse entered into a settlement. Pursuant to the settlement reached between Pulse and the Company, on October 9, 2018 the Company paid $930,000 to Pulse. The Company has also agreed to a permanent injunction and not to make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. There was no material impact on our revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

*Faulkner v. Akers Biosciences, Inc.*, No. 2:18-cv-10521 (D.N.J.) and *Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)*

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against the Company, John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with the Company, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018 (the "Faulkner Action"). The complaint alleged violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleged that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On June 20, 2018, Plaintiff David Gleason filed a class action complaint under the caption Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.) based on the same allegations and causes of action (the "Gleason Action"). On November 21, 2018, the Faulkner and Gleason Actions were consolidated under the Faulkner Action docket. The parties conducted a mediation on January 10, 2019, and agreed to a settlement in principle disposing of the consolidated action as to all Defendants, including the Individual Defendants. On March 8, 2019, the parties signed a settlement agreement, subject to approval by the Court, whereby the Company agreed to pay $2,250,000 in exchange for full releases and discharge of all claims against the Company. On the same day, Plaintiffs Tim Faulkner and David Gleason filed a motion for preliminary approval of the settlement and to establish notice procedures. On July 3, 2019, the Court granted the motion for preliminary approval and scheduled a final settlement hearing for November 8, 2019. On or about July 24, 2019, the Company's D&O insurer sent the settlement payment of $2,250,000 to the settlement agent for the class. On September 20, 2019, the Court granted the parties' request to adjourn the final settlement hearing and scheduled a final settlement hearing for December 20, 2019, at 11:00 a.m. On October 11, 2019, Plaintiffs Tim Faulkner and David Gleason filed motions for final approval of the proposed settlement and award of attorneys' fees, reimbursement of expenses, and award to Plaintiffs Tim Faulkner and David Gleason to be heard at the final settlement hearing on December 20, 2019.

*Watts v. Gormally, et al.,* No. 2:18-15992 (D.N.J.) *and Chan v. Gormally, et al*., No. 2:19-cv-4989 (D.N.J.)

On November 9, 2018, Cale Watts ("Watts Plaintiff") filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh ("Chan Plaintiffs") filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action (the "Chan Action"). The Chan Action further alleged that the Company should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to the Company and its shareholders. On March 22, 2019, the Watts Plaintiff filed a motion for preliminary approval of the proposed settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement ("Watts Motion for Preliminary Approval"). On April 1, 2019, the Chan Plaintiffs filed an Opposition to the Motion for Preliminary Approval and a Motion to Intervene and Stay Proceedings ("Motion to Intervene and Stay"). After multiple extensions of the Watts Motion for Preliminary Approval and the Chan Motion to Intervene and the defendants' opposition to the Motion to Intervene, the Watts Plaintiff, Chan Plaintiffs, and the defendants reached an agreement in principle to settle the Watts and Chan Actions that included corporate reforms and a payment of attorneys' fees of $325,000. On October 2, 2019, the Watts Plaintiff filed an Unopposed Motion for Preliminary Approval of the Settlement (the "Omnibus Motion for Preliminary Approval"). The court set a motion date for the Omnibus Motion for Preliminary Approval of November 4, 2019. The motion remains pending.

*Typenex Medical, LLC v. Akers Biosciences, Inc., JAMS Ref. No. 1450005929*

On November 15, 2018, Typenex Medical LLC ("Typenex"), a telemarketing entity with whom the Company had entered into a marketing and commission agreement dated September 30, 2016 (the "Marketing Contract"), filed an arbitration against the Company before JAMS ADR (the "Arbitration"), and an arbiter was appointed to the Arbitration on December 14, 2018. In the Arbitration, Typenex stated that it was seeking "at least" $220,500 based on the allegation that the Marketing Contract entitles Typenex to a commission on sales of certain of the Company's heparin-related products in the period two years from the Marketing Contract's expiration, and in the alternative, Typenex was seeking relief for breach of the implied covenant of good faith and fair dealing, and/or unjust enrichment. On July 19, 2019, the Company and Typenex executed a settlement agreement. Pursuant to the settlement agreement, the Company agreed to pay Typenex $50,000 in cash and to issue 1,667 shares of the Company's common stock. On December 2, 2019, the Company paid Typenex $50,000 in cash and issued 1,667 shares of the Company's common stock.

*NovoTek Therapeutics Inc. and NovoTek Pharmaceuticals Limited v. Akers Biosciences, Inc.*

On June 21, 2019, the Company received a complaint, filed by Novotek Therapeutics Inc., and Novotek Pharmaceuticals Limited (collectively, "Novotek"), Beijing-based entities, in the United States District Court for the District of New Jersey, alleging, among other things, breach of contract. Novotek is seeking, among other things, damages in the amount of $1,551,562, plus interest, disbursements and attorneys' fees. The Company vigorously disputes the allegations in the complaint and has retained counsel to defend it. On September 16, 2019, the Company filed a partial motion to dismiss the complaint which was submitted on November 4, 2019. The Company is not yet able to determine the amount of the Company's exposure, if any.

*Neelima Varma v. Akers Biosciences, Inc. and St. David's Healthcare Partnership, L.P., LLP CAUSE NO: D-1-GN-19-004262*

On July 25, 2019, the Company was notified that on July 23, 2019, a complaint was filed by Neelima Varma, against the Company and St. David's Healthcare Partnership, L.P., LLP ("St. David's"), in the district court of Travis County, Texas, alleging, among other things, negligence, gross negligence and strict product liability, breach of express warranty, breach of implied warranty and fraudulent misrepresentation and omission in connection with allegedly erroneous results generated by the PIFA Heparin/PF4 Rapid Assay. The complaint argues that the allegedly erroneous results caused St. David's to continue with a course of treatment that ultimately contributed to the loss of the plaintiff's left leg. Ms. Varma is seeking aggregate monetary relief from the Company and St. David's in excess of $1,000,000. On September 20, 2019, the Company filed the original answer to plaintiff's original petition and on October 1, 2019, the Company received from plaintiff their first interrogatories and request for production of documents. The Company carries product liability insurance. The insurance carrier has provided notice that it has reserved certain rights. The Company and its insurance carrier will contest this complaint vigorously. The Company believes that its product liability insurance coverage will be adequate to cover the potential exposure from defending against this matter and any judgments, fines, or settlement costs directly resulting from this matter.

*Douglas Carrara v. Akers Biosciences, Inc., John Does 1-10, and XYZ Corp. 1-10, Docket No. ESX-L-5272-19 (N.J. Super. Ct., Essex County):*

Douglas Carrara, a former executive, has sued the Company over the termination of his employment. The executive seeks contractual severance pay in the amount of $200,000. The executive asserts that the termination was without cause within the meaning of his employment agreement, which provides for severance of one year's salary in the event of termination without cause. The executive also seeks indemnification for approximately $10,000 in attorneys' fees that he contends he incurred in regard to company business. On August 29, 2019, the Company filed an answer to the second amended complaint and the parties have exchanged documents and interrogatories as part of the discovery process. No trial date or discovery cut off has been set. With regard to both claims, the executive seeks to recover his attorneys' fees under a fee-shifting provision in his employment agreement.

*Other*

A former executive has threatened to sue the Company over the termination of the executive's employment. The executive contends that the termination was in retaliation for complaints to the employer protected under the California whistleblower protection laws. The executive also contends that the Company failed to pay a bonus in violation of an employment contract. As of the date of this prospectus, the Company has resolved the matter with the former executive.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, the following is a description of transactions to which we were a participant or will be a participant to, in which:

- the amounts involved exceeded or will exceed the lesser of 1% of the average of our total assets for the last two completed fiscal years or $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Effective on October 5, 2018, the Board of Directors appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr. Yeaton is the managing principal of FCS and the Company has an ongoing relationship with FCS, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the year ended December 31, 2018, the Company expensed $104,749 to FCS (including fees incurred prior to the date that Mr. Yeaton began to serve as an officer of the Company) in connection with these services. As of September 30, 2019, the Company owed FCS $41,819. On November 1, 2019, the Board of Directors of the Company provided Mr. Howard R. Yeaton with sixty (60) days' notice of its intent to terminate him from each of his officer positions as Chief Executive Officer and interim Chief Financial Officer of the Company.

Compensation arrangements for our named executive officers and directors are described in the section titled "Executive Compensation" in our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this prospectus. Disclosure in this Certain Relationships and Related Party Transactions and the section "Executive Compensation" in our Annual Report on Form 10-K for the year ended December 31, 2018 do not give effect to the Reverse Stock Split.

## DESCRIPTION OF OUR CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our articles of incorporation and bylaws, which have been publicly filed with the SEC. See "Where You Can Find More Information."

Our authorized capital stock consists of 52,604,167 shares, of which 2,604,167 are common stock, without par value, and 50,000,000 are preferred stock, without par value.

As described elsewhere in this prospectus, we do not have a sufficient number of authorized shares of common stock to cover the shares issuable upon the conversion of Series C Preferred Stock issuable in this offering. Because we do not have sufficient number of authorized shares available, before any shares of Series C Preferred Stock can become convertible, we will need to receive stockholder approval of the Charter Amendment to sufficiently increase our authorized shares of common stock to cover the conversion of all shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock. We have agreed in the securities purchase agreement for this offering to use our reasonable best efforts to obtain such approval within 60 days from the date of this prospectus We intend to seek stockholder approval to amend our amended and restated certificate of incorporation, as amended, to increase the number of authorized shares of common stock from 2,604,167 to 100,000,000 shares at our 2019 annual meeting of stockholders scheduled to be held on December 30, 2019. If approved by our stockholders, we intend to file the Charter Amendment with the Secretary of State of New Jersey as soon as practicable following the special meeting or the annual meeting, as the case may be, and the Charter Amendment will be effective upon such filing.

We cannot assure you that we will be able to obtain requisite stockholder approval of the Charter Amendment. If the Charter Amendment is not approved by our stockholders, our amended and restated certificate of incorporation, as amended, will continue as currently in effect. In the event our stockholders do not approve the Charter Amendment, the Series C Preferred Stock underlying investor warrants issued in this offering will not be convertible into common stock and the value of the investor warrants and the Series C Preferred Stock will be negatively affected.

### Common Stock

#### *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 of directors 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 of directors 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.

#### *Options, Warrants and RSUs*

As of December 5, 2019, we had 39 shares issuable upon exercise of outstanding options, 87,947 shares issuable upon the exercise of warrants and 15,603 shares issuable upon the vesting of RSUs. The shares issuable upon the vesting of RSUs are not issuable until the increase in the number authorized shares of common stock is approved by the stockholders of the Company. There are no other outstanding warrants, options or RSUs at this time. After the closing of the offering, 159,200 shares of common stock will be issuable upon exercise of the placement agent warrants and 1,990,000 shares of Series C Preferred Stock will be issuable upon the exercise of the investor warrants.

### Preferred Stock

We may issue any class of preferred stock in any series. Our board of directors has the authority, subject to limitations prescribed under New Jersey law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding. 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 the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of common stock and the voting and other rights of the holders of common stock.

Following this offering, we will have designated 1,990,000 shares of our preferred stock as Series C Convertible Preferred Stock. See "Description of Securities We Are Offering — Series C Convertible Preferred Stock" for a description of our Series C Convertible Preferred Stock.

***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.

**The NASDAQ Capital Market Listing**

Our common stock is listed on the NASDAQ Capital Market under the symbol "AKER." Our common stock is currently subject to a notice of delisting and has a hearing scheduled with a NASDAQ Hearings Panel on December 12, 2019 at 9:00 a.m. Eastern Time.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

## DESCRIPTION OF THE SECURITIES WE ARE OFFERING

We are offering 613,500 Class A Units and 1,376,500 Class B Units. Each Class A Unit consists of one share of our common stock and a warrant to purchase one share of our Series C Preferred Stock. Each Class B Unit consists of one pre-funded warrant to purchase one share of our common stock and a warrant to purchase one share of our Series C Preferred Stock. The Class A Units and the Class B Units will not be certificated. The shares of common stock or the pre-funded warrants, as the case may be, and investor warrants included in the Units are immediately separable and will be issued separately in this offering. We are also registering the shares of our common stock included in Class A Units and issuable upon exercise of the pre-funded warrants, the investor warrants, the pre-funded warrants, and the shares of Series C Preferred Stock issuable upon exercise of the investor warrants offered hereby.

**Common Stock**

The material terms and provisions of our common stock are described under the caption "Description of Capital Stock" starting on page 44 of this prospectus.

**Series C Convertible Preferred Stock**

*The following summary of certain terms and provisions of the Series C Preferred Stock that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of, the Certificate of Designations of the Series C Preferred Stock. Prospective investors should carefully review the terms and provisions of the Certificate of Designations of the Series C Preferred Stock for a complete description of the terms and conditions of the Series C Preferred Stock. This description is subject to and qualified entirely by the terms of the Certificate of Designations of the Series C Preferred Stock to be filed as an exhibit to the registration statement of which this prospectus is a part.*

General. Our Board of Directors is authorized to issue up to 50,000,000 shares of preferred stock in one or more series without shareholder approval. Our Board of Directors may determine the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualification, limitations and restrictions, of each series of preferred stock. Our Board of Directors has designated 1,990,000 shares of preferred stock as Series C Convertible Preferred Stock, which we refer to herein as the Series C Preferred Stock.

*Rank.* The Series C Preferred Stock ranks (1) on parity with common stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series C Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series C Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series C Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

*Conversion*. We do not have a sufficient number of authorized shares of common stock to cover the shares issuable upon the conversion of Series C Preferred Stock. Because we do not have a sufficient number of authorized shares of common stock to cover the shares issuable upon the conversion of Series C Preferred Stock underlying the investor warrants issued in this offering, before any shares of Series C Preferred Stock can become convertible, we will need to receive stockholder approval of the Charter Amendment to sufficiently increase our authorized shares of common stock to cover the conversion of all shares of Series C Preferred Stock issuable upon exercise of the investor warrants being issued in this offering into common stock. We have agreed in the securities purchase agreement for this offering to use our best efforts to obtain such approval within 60 days from the date of this prospectus. We are currently seeking stockholder approval to amend our amended and restated certificate of incorporation, as amended, to increase the number of authorized shares of common stock from 2,604,167 to 100,000,000 shares at our 2019 annual meeting of stockholders scheduled to be held on December 30, 2019. We cannot assure you that we will be able to obtain requisite stockholder approval of the Charter Amendment. Because we do not have sufficient number of authorized shares of common stock to cover the shares issuable upon the conversion of Series C Preferred Stock issuable upon exercise of the investor warrants issued in this offering, the Series C Preferred Stock will not be convertible until the next business day after the Charter Amendment Date (which is the date on which we publicly announce through the filing of a Current Report on Form 8-K that the Charter Amendment has been filed with the Secretary of State of the State of New Jersey). Each share of the Series C Preferred Stock is convertible into one (1) share of common stock, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of common stock if, as a result of such conversion, the holder would own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions. In the event our stockholders do not approve the Charter Amendment, the Series C Preferred Stock will not be convertible into common stock and the value of Series C Preferred Stock will be negatively affected.

*Dividends.* In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends are payable on shares of Series C Preferred Stock.

*Voting Rights*. Except as provided in the Certificate of Designation or as otherwise required by law, the holders of Series C Preferred Stock will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series C Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock, or enter into any agreement with respect to the foregoing.

*Liquidation Rights*. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, pari passu with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described below.

*Exchange Listing.* We do not plan on making an application to list the shares of Series C Preferred Stock on the NASDAQ, any national securities exchange or other nationally recognized trading system. Our common stock issuable upon conversion of the Series C Preferred Stock is listed on the NASDAQ.

*Failure to Deliver Conversion Shares.* If we fail to timely deliver shares of common stock upon conversion of the Series C Preferred Stock (the "Conversion Shares") within the time period specified in the Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $50 per trading day (increasing to $100 per trading day after the third trading day and $200 per trading day after the tenth trading day) for each $5,000 of Conversion Shares for which the Series C Preferred Stock converted which are not timely delivered. If we make such liquidated damages payments, we are not also obligated to make Buy-In payments with respect to the same Conversion Shares.

*Compensation for Buy-In on Failure to Timely Deliver Shares.* If we fail to timely deliver the Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Buy-In"), then we are obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Conversion Shares that we were required to deliver times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series C Preferred Stock and equivalent number of Conversion Shares for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had we timely complied with its conversion and delivery obligations.

*Subsequent Rights Offerings; Pro Rata Distributions.* If we grant, issue or sell any common stock equivalents pro rata to the record holders of any class of shares of common stock (the "Purchase Rights"), then a holder of Series C Preferred Stock will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon conversion of the Series C Preferred Stock (without regard to any limitations on conversion). If we declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of common stock, then a holder of Series C Preferred Stock is entitled to participate in such distribution to the same extent as if the holder had held the number of shares of common stock acquirable upon complete conversion of the Series C Preferred Stock (without regard to any limitations on conversion).

*Fundamental Transaction.* If, at any time while the Series C Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding common stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a "Series C Preferred Stock Fundamental Transaction"), then upon any subsequent conversion of Series C Preferred Stock, the holder will receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Series C Preferred Stock Fundamental Transaction (without regard to the Beneficial Ownership Limitation), the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Series C Preferred Stock Alternate Consideration") receivable as a result of such Series C Preferred Stock Fundamental Transaction by a holder of the number of shares of common stock for which the Series C Preferred Stock is convertible immediately prior to such Series C Preferred Stock Fundamental Transaction (without regard to the Beneficial Ownership Limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Series C Preferred Stock Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Series C Preferred Stock Fundamental Transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a Series C Preferred Stock Fundamental Transaction, then the holder will be given the same choice as to the Series C Preferred Stock Alternate Consideration it receives upon automatic conversion of the Series C Preferred Stock following such Fundamental Transaction.

**Pre-Funded Warrants and Investor Warrants**

*The following summary of certain terms and provisions of the pre-funded warrants and the investor warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of, the pre-funded warrants and investor warrants. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrants and form of investor warrants for a complete description of the terms and conditions of the pre-funded warrants and investor warrants. This description is subject to and qualified entirely by the terms of the forms of pre-funded warrants and investor warrants to be filed as an exhibit to the registration statement of which this prospectus is a part.*

*Pre-Funded Warrants*

The term "pre-funded" refers to the fact that the purchase price of our common stock in this offering includes almost the entire exercise price that will be paid upon exercise of the pre-funded warrants, $3.9999 per share, except for a nominal remaining exercise price of $0.0001 per share. The purpose of the pre-funded warrants is to enable investors that may have restrictions on their ability to beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering the opportunity to invest capital into the Company without triggering their ownership restrictions, by receiving pre-funded warrants in lieu of our common stock which would result in such ownership of more than 4.99% (or, at the election of the purchaser, 9.99%), and receive the ability to exercise their option to purchase the shares underlying the pre-funded warrants at such nominal price at a later date.

*Duration*. The pre-funded warrants offered hereby will be immediately exercisable on the date of issuance and may be exercised at any time until the pre-funded warrants are exercised in full.

*Exercise Limitation.* A holder will not have the right to exercise any portion of the pre-funded warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61$^{st}$ day after such election. Purchasers of Class B Units in this offering may also elect prior to the issuance of the Class B Units to have the initial exercise limitation set at 9.99% of our outstanding common stock.

*Exercise Price.* The pre-funded warrants will have an exercise price of $0.0001 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Cashless Exercise.* If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

*Transferability.* Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned without our consent.

*Exchange Listing.* There is no established public trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

*Fundamental Transactions.* If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the pre-funded warrants with the same effect as if such successor entity had been named in the pre-funded warrants itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the pre-funded warrant following such fundamental transaction.

*Rights as a Stockholder.* Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a pre-funded warrants does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the pre-funded warrant.

*Investor Warrants*

Duration. The investor warrants offered hereby will entitle the holders thereof to purchase shares of our Series C Preferred Stock from the date of issuance until five (5) year anniversary of the Charter Amendment Date.

*Exercise Price.* The investor warrants will have an exercise price of $4.00 per share of Series C Preferred Stock. The exercise price and the number of shares of Series C Preferred Stock issuable upon exercise is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Cashless Exercise.* If, at the time a holder exercises its investor warrants, a registration statement registering the issuance or resale of the shares of Series C Preferred Stock underlying the investor warrants under the Securities Act is not then effective or available for the issuance or resale of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the investor warrants.

*Exchange Listing.* There is no established public trading market for the investor warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the investor warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the investor warrants will be limited.

*Fundamental Transactions.* If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the investor warrants with the same effect as if such successor entity had been named in the investor warrants itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the investor warrant following such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our board, the holders of the investors warrants have the right to require us or a successor entity to redeem the investor warrants for cash in the amount of the Black-Scholes value of the unexercised portion of the investor warrant as of the date of the consummation of the fundamental transaction; provided, however, in the event of a fundamental transaction which is not approved by our board and not within the control of the Company, holder shall only be entitled to receive from the Company or any successor entity, as of the date of consummation of such fundamental transaction, the same type or form of consideration, at the Black Scholes value of the unexercised portion of the investor warrant that is being offered and paid to the holders of common stock of the Company in connection with the fundamental transaction.

*Rights as a Stockholder.* Except as otherwise provided in the investor warrants or by virtue of such holder's ownership of shares of our common stock, the holder of an investor warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the investor warrant.

*Transferability*. Subject to applicable laws and a standard legend with regard to restriction on transfer only in compliance with a public offering or an available exemption therefrom, the warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

*Waivers and Amendments.* No term of the warrants may be amended or waived without the written consent of the holder of such warrant.

## PLAN OF DISTRIBUTION

Pursuant to an engagement agreement dated October 18, 2019, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent to solicit offers to purchase the securities offered pursuant to this prospectus on a reasonable best efforts basis. The terms of this offering are subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent may engage sub-agents or selected dealers to assist with the offering.

We will enter into a securities purchase agreement directly with certain institutional investors, at the investor's option, which purchase our securities in this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

The placement agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. The placement agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about December 9, 2019.

**Fees and Expenses**

The following table show the per Class A Unit and per Class B Unit and total placement agent fees we will pay in connection with the sale of the securities in this offering.

| | Per Class A Unit | Per Class B Unit |
|---|---|---|
| Placement Agent Fees | $ 0.30 | $ 0.30 |
| Total | $ 184,050.00 | $ 412,950.00 |

We have agreed to pay the placement agent a total cash fee equal to 7.5% of the gross proceeds of this offering and a management fee equal to 1.0% of the gross proceeds raised in this offering. We will also pay the placement agent a non-accountable expense allowance of $40,000 and $10,000 for the clearing expenses of the placement agent and reimburse the placement agent's legal fees and expenses in an amount up to $75,000 in connection with this offering. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately $171,000.

**Placement Agent Warrants**

In addition, we have agreed to issue to the placement agent warrants to purchase 159,200 shares of common stock (equal to 8.0% of the aggregate number of shares of common stock (i) included within the Class A Units and (ii) issuable upon the exercise of the pre-funded warrants included within the Class B Units that are, in each case, placed in this offering to investors) at an exercise price of $5.00 per share (equal to 125% of the per unit public offering price for the Class A Units), exercisable for five years from the date of the effectiveness of this offering. The placement agent warrants are registered on the registration statement of which this prospectus is a part. The placement agent warrants will have substantially the same terms as the warrants being sold to the investors in this offering. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares of common stock issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in 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) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

**Right of First Refusal**

We have also agreed to give the placement agent, subject to the completion of this offering, certain rights of first refusal for a period of twelve months with respect to certain transactions, including any further capital raising transactions undertaken by us.

**Tail Financing Payments**

We have also agreed to pay the placement agent a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the placement agent 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 9-month period following expiration or termination of our engagement of the placement agent.

**Lock-Up Agreements**

We and each of our officers and directors have agreed not to offer, pledge, sell, contract to sell, grant any option or contract to purchase, purchase any option or contract to sell, or otherwise dispose of, directly or indirectly, any common stock or any securities convertible into, exercisable for, or exchangeable for common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock for a period of 90 days after the effective date of the registration statement of which this prospectus is a part. The placement agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

**Indemnification**

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

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

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

**Determination of Offering Price**

The public offering price of the securities we are offering and the exercise price and other terms of the warrants were negotiated between us and the investors, in consultation with the placement agent based on the trading of our common stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering include, among other things, the history and prospects of the Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

**Listing**

Our common stock is currently traded on NASDAQ under the symbol "AKER." Our common stock is currently subject to a notice of delisting and has a hearing scheduled with a NASDAQ Hearings Panel on December 12, 2019 at 9:00 a.m. Eastern Time.

**Other Relationships**

From time to time, the placement agent 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. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

## LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. Haynes and Boone, LLP, New York, New York is acting as counsel for the placement agent in connection with certain legal matters related to this offering.

## 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, 2018, as filed on April 1, 2019, 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 MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our securities, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement is this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. We are subject to the informational requirements of the Exchange Act and in accordance therewith file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. The registration statement and the documents referred to below under "Incorporation of Documents By Reference" are also available on our website, www.akersbio.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

## INCORPORATION OF DOCUMENTS BY REFERENCE

This prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. The Securities and Exchange Commission permits us to "incorporate by reference" the information contained in documents we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Information that we file later with the Securities and Exchange Commission will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the Securities and Exchange Commission, and incorporate by reference in this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Commission on April 1, 2019;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC on May 20, 2019, for the quarter ended June 30, 2019, filed with the SEC on August 14, 2019 and for the quarter ended September 30, 2019, filed with the SEC on November 14, 2019;
- Definitive Proxy Statement on Schedule 14A filed on February 5, 2019, and Definitive Proxy Statement on Schedule 14A, filed on November 12, 2019, as amended on December 5, 2019; and
- Current Reports on Form 8-K, filed on March 5, 2019, May 16, 2019, June 21, 2019, September 25, 2019, November 1, 2019, November 8, 2019, November 29, 2019 and December 4, 2019 (other than any portions thereof deemed furnished and not filed); and

In addition, all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, prior to the termination of the offering (excluding any information furnished rather than filed) shall be deemed to be incorporated by reference into this prospectus.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have "furnished" to the SEC pursuant to the Securities Exchange Act of 1934, as amended shall be incorporated by reference into this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to:

Akers Biosciences, Inc.
201 Grove Road
Thorofare, New Jersey 08086
Telephone (856) 848-8698

You also may access these filings on our website at http://www.akersbio.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement. Any statement contained herein or in any document incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for purposes of the registration statement of which this prospectus forms a part to the extent that a statement contained in any other subsequently filed document which also is or is deemed to be incorporated by reference modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed to constitute a part of the registration statement of which this prospectus forms a part, except as so modified or superseded.

**You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.**

**Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.**


**613,500 Class A Units consisting of Common Stock and Warrants or**
**1,376,500 Class B Units consisting of Pre-funded Warrants and Warrants**
**1,376,500 Shares of Common Stock Underlying the Pre-funded Warrants and**
**1,990,000 shares of Series C Convertible Preferred Stock Underlying the Warrants**

**PROSPECTUS**

## H.C. Wainwright & Co.

**December 5, 2019**