EDGAR SUBMISSION SUMMARY

Submission Type	**253G2**
Live File	**On**
Return Copy	**On**
Exchange	**NONE**
Confirming Copy	**Off**
Filer CIK	**0001723443**
Filer CCC	**xxxxxxxx**
File Number:	**024-10845**
Notify via Filing website Only	**Off**
Emails	**file@discountedgar.com**

Documents

Form Type	File Name	Description
253G2	**insitu_posam.htm**	**253G2**
GRAPHIC	**insitu_1aimg1.jpg**	
GRAPHIC	**insitu_1aimg2.jpg**	
GRAPHIC	**insitu_1aimg3.jpg**	
GRAPHIC	**insitu_1aimg4.jpg**	
GRAPHIC	**insitu_1aimg6.jpg**	
GRAPHIC	**insitu_1aimg7.jpg**	

Module and Segment References

Filed Pursuant to Rule 253(g)(2)
File No. 024-10845

817,117 Shares of Class A Common Stock at $8.20 per Share
Minimum Investment: 300 Shares ($2,460.00)
Maximum Offering: $6,700,361.00

Offering Circular dated October 19, 2019

This offering (the "Offering") pursuant to Regulation A consists of Class A Common Stock (the "Shares" or individually, each a "Share") that is being offered on a "best efforts" basis, which means that there is no guarantee that any minimum amount will be sold. The Shares are being offered and sold by InSitu Biologics, Inc., a Delaware Corporation ("InSitu Biologics" or the "Company"). We sold 275,661 shares at $5.75 per share, 43,126 shares at $6.85 per share, 31,588 shares at $6.90, and 82,877 Shares at $8.00 per share since our Offering was qualified. Due to the popularity of the shares and in an effort to maximize shareholder value, we are increasing our share price to $8.20 per share. As of the date of this Offering Circular, there are 2,867,114 Class A shares outstanding. The minimum investment amount has been adjusted to $2,460.00 per investor (40 shares.) The Shares are being offered on a best efforts basis to an unlimited number of accredited investors and an unlimited number of non-accredited investors only by the Company. The maximum aggregate amount of the Shares offered is $10,000,003.20 (the "Total Maximum Offering") and includes the remaining shares at a remaining total of $6,700,361 ("Maximum Offering.")

PLEASE REVIEW ALL RISK FACTORS ON PAGE 9 BEFORE MAKING AN INVESTMENT IN THIS COMPANY. AN INVESTMENT IN THIS COMPANY SHOULD ONLY BE MADE IF YOU ARE CAPABLE OF EVALUATING THE RISKS AND MERITS OF THIS INVESTMENT AND IF YOU HAVE SUFFICIENT RESOURCES TO BEAR THE ENTIRE LOSS OF YOUR INVESTMENT, SHOULD THAT OCCUR.

THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION DOES NOT PASS UPON THE MERITS OF OR GIVE ITS APPROVAL TO ANY SECURITIES OFFERED OR THE TERMS OF THE OFFERING, NOR DOES IT PASS UPON THE ACCURACY OR COMPLETENESS OF ANY OFFERING CIRCULAR OR OTHER SELLING LITERATURE. THESE SECURITIES ARE OFFERED PURSUANT TO AN EXEMPTION FROM REGISTRATION WITH THE COMMISSION; HOWEVER, THE COMMISSION HAS NOT MADE AN INDEPENDENT DETERMINATION THAT THE SECURITIES OFFERED HEREUNDER ARE EXEMPT FROM REGISTRATION.

Because these securities are being offered on a "best efforts" basis, the following disclosures are hereby made:

	Price to Public	Commissions (1)	Proceeds to Company (2)	Proceeds to Other Persons (3)
Minimum Investment	$ 2,460.00	$ 24.60	$ 2,435.40	None
Maximum Offering	$ 6,700,361	$ 67,003	$ 6,633,358	None

(1) We recently entered into an agreement with Sageworks Capital, LLC ("Sageworks") to assist in the sale of our securities. Sageworks was paid a one-time fee of $10,000 and 1% of the securities sold. See "PLAN OF DISTRIBUTION."

(2) Does not reflect payment of expenses of this offering, which are estimated to not exceed $700,001 and which include, among other things, legal fees, accounting costs, reproduction expenses, due diligence, marketing, consulting, administrative services other costs of blue sky compliance, and actual out-of-pocket expenses incurred by the Company selling the Shares, but which do not include administrative fees paid to technology providers. See the "Plan of Distribution" for details regarding the compensation payable in connection with this offering. This amount represents the proceeds of the offering to the Company, which will be used as set out in "USE OF PROCEEDS TO COMPANY."

(3) There are no finder's fees or other fees being paid to third parties from the proceeds, other than those disclosed below. See "PLAN OF DISTRIBUTION."

GENERALLY, NO SALE MAY BE MADE TO YOU IN THIS OFFERING IF THE AGGREGATE PURCHASE PRICE YOU PAY IS MORE THAN 10% OF THE GREATER OF YOUR ANNUAL INCOME OR NET WORTH. DIFFERENT RULES APPLY TO ACCREDITED INVESTORS AND NON-NATURAL PERSONS. BEFORE MAKING ANY REPRESENTATION THAT YOUR INVESTMENT DOES NOT EXCEED APPLICABLE THRESHOLDS, WE ENCOURAGE YOU TO REVIEW RULE 251(D)(2)(I)(C) OF REGULATION A. FOR GENERAL INFORMATION ON INVESTING, WE ENCOURAGE YOU TO REFER TO WWW.INVESTOR.GOV.

2155 Woodlane Drive, Suite 102
Woodbury, MN 55125
651-337-4799
InSitu Biologics, Inc.

The Shares are being offered pursuant to Regulation A of Section 3(b) of the Securities Act of 1933, as amended, for Tier 2 offerings. The Shares will only be issued to purchasers who satisfy the requirements set forth in Regulation A. The offering is expected to expire on the first of: (i) all of the Shares offered are sold; or (ii) unless sooner terminated by the Company's CEO. Funds shall be deposited in a Company account. Funds will be promptly refunded without interest, for sales that are not consummated. All funds received shall be held only in a non-interest bearing bank account. Upon each closing under the terms as set out in this Offering Circular, funds will be immediately transferred to the Company where they will be available for use in the operations of the Company's business in a manner consistent with the "USE OF PROCEEDS TO COMPANY" in this Offering Circular. This Offering may remain open for a twelve (12) month period but may extend past the Closing Date at the discretion of the Company and in accordance with the rules and provisions of Regulation A of the JOBS Act.

THIS OFFERING CIRCULAR DOES NOT CONSTITUTE AN OFFER OR SOLICITATION IN ANY JURISDICTION IN WHICH SUCH AN OFFER OR SOLICITATION WOULD BE UNLAWFUL. NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS CONCERNING THE COMPANY OTHER THAN THOSE CONTAINED IN THIS OFFERING CIRCULAR, AND IF GIVEN OR MADE, SUCH OTHER INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON.

PROSPECTIVE INVESTORS ARE NOT TO CONSTRUE THE CONTENTS OF THIS OFFERING CIRCULAR, OR OF ANY PRIOR OR SUBSEQUENT COMMUNICATIONS FROM THE COMPANY OR ANY OF ITS EMPLOYEES, AGENTS OR AFFILIATES, AS INVESTMENT, LEGAL, FINANCIAL OR TAX ADVICE.

BEFORE INVESTING IN THIS OFFERING, PLEASE REVIEW ALL DOCUMENTS CAREFULLY, ASK ANY QUESTIONS OF THE COMPANY'S MANAGEMENT THAT YOU WOULD LIKE ANSWERED AND CONSULT YOUR OWN COUNSEL, ACCOUNTANT AND OTHER PROFESSIONAL ADVISORS AS TO LEGAL, TAX AND OTHER RELATED MATTERS CONCERNING THIS INVESTMENT.

NASAA UNIFORM LEGEND

FOR RESIDENTS OF ALL STATES: THE PRESENCE OF A LEGEND FOR ANY GIVEN STATE REFLECTS ONLY THAT A LEGEND MAY BE REQUIRED BY THAT STATE AND SHOULD NOT BE CONSTRUED TO MEAN AN OFFER OR SALE MAY BE MADE IN A PARTICULAR STATE. IF YOU ARE UNCERTAIN AS TO WHETHER OR NOT OFFERS OR SALES MAY BE LAWFULLY MADE IN ANY GIVEN STATE, YOU ARE HEREBY ADVISED TO CONTACT THE COMPANY. THE SECURITIES DESCRIBED IN THIS OFFERING CIRCULAR HAVE NOT BEEN REGISTERED UNDER ANY STATE SECURITIES LAWS (COMMONLY CALLED "BLUE SKY" LAWS).

IN MAKING AN INVESTMENT DECISION INVESTORS MUST RELY ON THEIR OWN EXAMINATION OF THE PERSON OR ENTITY CREATING THE SECURITIES AND THE TERMS OF THE OFFERING, INCLUDING THE MERITS AND RISKS INVOLVED. THESE SECURITIES HAVE NOT BEEN RECOMMENDED BY ANY FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THE FOREGOING AUTHORITIES HAVE NOT CONFIRMED THE ACCURACY OR DETERMINED THE ADEQUACY OF THIS DOCUMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

NOTICE TO FOREIGN INVESTORS

IF THE PURCHASER LIVES OUTSIDE THE UNITED STATES, IT IS THE PURCHASER'S RESPONSIBILITY TO FULLY OBSERVE THE LAWS OF ANY RELEVANT TERRITORY OR JURISDICTION OUTSIDE THE UNITED STATES IN CONNECTION WITH ANY PURCHASE OF THE SECURITIES, INCLUDING OBTAINING REQUIRED GOVERNMENTAL OR OTHER CONSENTS OR OBSERVING ANY OTHER REQUIRED LEGAL OR OTHER FORMALITIES. THE COMPANY RESERVES THE RIGHT TO DENY THE PURCHASE OF THE SECURITIES BY ANY FOREIGN PURCHASER.

Forward Looking Statement Disclosure

References to the Form 1-A refer to our Form 1-A filed on June 5, 2018 and any amendment thereto, including those amendments on a Post Effective Amendment on March 27, 2019.

The Form 1-A, Offering Circular, and any documents incorporated by reference herein or therein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in the Form 1-A, Offering Circular, and any documents incorporated by reference are forward-looking statements. Forward-looking statements give the Company's current reasonable expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "estimate," "expect," "project," "plan," "intend," "believe," "may," "should," "can have," "likely" and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events. The forward-looking statements contained in the Form 1-A, Offering Circular, and any documents incorporated by reference herein or therein are based on reasonable assumptions the Company has made in light of its industry experience, perceptions of historical trends, current conditions, expected future developments and other factors it believes are appropriate under the circumstances. As you read and consider the Form 1-A, Offering Circular, and any documents incorporated by reference, you should understand that these statements are not guarantees of performance or results. They involve risks, uncertainties (many of which are beyond the Company's control) and assumptions. Although the Company believes that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect its actual operating and financial performance and cause its performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of these assumptions prove incorrect or change, the Company's actual operating and financial performance may vary in material respects from the performance projected in these forward-looking statements. Any forward-looking statement made by the Company in the Form 1-A, Offering Circular or any documents incorporated by reference herein speaks only as of the date of the Form 1-A, Offering Circular or any documents incorporated by reference herein. Factors or events that could cause our actual operating and financial performance to differ may emerge from time to time, and it is not possible for the Company to predict all of them. The Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

About The Form 1-AOffering Circular

In making an investment decision, you should rely only on the information contained in the Form 1-A and Offering Circular. The Company has not authorized anyone to provide you with information different from that contained in the Form 1-A and Offering Circular. We are offering to sell, and seeking offers to buy the Shares only in jurisdictions where offers and sales are permitted. You should assume that the information contained in the Form 1-A and Offering Circular is accurate only as of the date of the Form 1-A and Offering Circular, regardless of the time of delivery of the Form 1-A and Offering Circular. Our business, financial condition, results of operations, and prospects may have changed since that date. Statements contained herein as to the content of any agreements or other documents are summaries and, therefore, are necessarily selective and incomplete and are qualified in their entirety by the actual agreements or other documents. The Company will provide the opportunity to ask questions of and receive answers from the Company's management concerning terms and conditions of the Offering, the Company or any other relevant matters and any additional reasonable information to any prospective investor prior to the consummation of the sale of the Shares. The Form 1-A and Offering Circular do not purport to contain all of the information that may be required to evaluate the Offering and any recipient hereof should conduct its own independent analysis. The statements of the Company contained herein are based on information believed to be reliable. No warranty can be made as to the accuracy of such information or that circumstances have not changed since the date of the Form 1-A and Offering Circular. The Company does not expect to update or otherwise revise the Form 1-A, Offering Circular or other materials supplied herewith. The delivery of the Form 1-A and Offering Circular at any time does not imply that the information contained herein is correct as of any time subsequent to the date of the Form 1-A and Offering Circular. The Form 1-A and Offering Circular are submitted in connection with the Offering described herein and may not be reproduced or used for any other purpose.

EXEMPTIONS UNDER JUMPSTART OUR BUSINESS STARTUPS ACT

We are an emerging growth company. An emerging growth company is one that had total annual gross revenues of less than $1,000,000,000 (as such amount is indexed for inflation every 5 years by the Commission to reflect the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics, setting the threshold to the nearest 1,000,000) during its most recently completed fiscal year. We would lose our emerging growth status if we were to exceed $1,000,000,000 in gross revenues. We are not sure this will ever take place.

Because we are an emerging growth company, we have the exemption from Section 404(b) of Sarbanes-Oxley Act of 2002 and Section 14A(a) and (b) of the Securities Exchange Act of 1934. Under Section 404(b), we are now exempt from the internal control assessment required by subsection (a) that requires each independent auditor that prepares or issues the audit report for the issuer shall attest to, and report on, the assessment made by the management of the issuer. We are also not required to receive a separate resolution regarding either executive compensation or for any golden parachutes for our executives so long as we continue to operate as an emerging growth company.

We hereby elect to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1).

- We will lose our status as an emerging growth company in the following circumstances:
- The end of the fiscal year in which our annual revenues exceed $1 billion.
- The end of the fiscal year in which the fifth anniversary of our IPO occurred.
- The date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt.
- The date on which we qualify as a large accelerated filer.

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SUMMARY

The following summary is qualified in its entirety by the more detailed information appearing elsewhere in this Offering Circular and/or incorporated by reference in this Offering Circular. For full offering details, please (1) thoroughly review the Form 1-A filed with the Securities and Exchange Commission (2) thoroughly review this Offering Circular and (3) thoroughly review any attached documents to or documents referenced in, the Form 1-A and Offering Circular.

Type of Stock Offering:	Class A Common Stock
Price Per Share:	$8.20
Minimum Investment:	$2,460 per investor (300 shares of Class A Common Stock)
Maximum Offering:	$10,000,000. This amount includes the amount already raised by the Company under Regulation A. Currently, there is $ 6,700,361 remaining. The Company will not accept investments greater than the Maximum Offering amount.
Maximum Shares Offered:	817,117 remaining Shares of Class A Common Stock at $8.20 per share for a total of $ 6,700,361.
Use of Proceeds:	See the description in section entitled “USE OF PROCEEDS TO COMPANY “ on page 32 herein.
Voting Rights:	The Shares have voting rights that are pari pasu with the Preferred Shares (currently none outstanding) with one vote per share. The Class B Shares have a two (2) votes per every share. See the description of the voting rights all the Company’s other classes of stock on page 64 herein.
Length of Offering:	Shares will be offered on a continuous basis until either (1) the maximum number of Shares or sold; (2) if the Company in its sole discretion withdraws this Offering.
Implicit Valuation:	The implicit valuation of the Company’s outstanding shares is calculated by multiplying the number of shares currently outstanding by the offering price per share.

The Offering

Class B Common Stock Outstanding (1)	3,000,000 (post split)
Class A Common Stock in this Offering (2)	817,117 Shares remaining (post split)
Class A Common Stock Outstanding	2,867,114 (post split and reverse split of founder shares)
Preferred Stock Outstanding (3)	0 Shares
Total Stock to be outstanding after the offering (4)	10,211,508 Shares

1. There are 3 classes of stock in the Company at present: Preferred Stock, Class A Common Stock, and Class B Common Stock. For a full description of the rights of each class of stock, please see the section of this Offering Circular entitled “Securities Being Offered “on page 64 below.

2. The total number of Shares of Class A Common Stock assumes that the maximum number of Shares are sold in this offering. The Company has sold 275,661 shares at $5.75 per share, 43,126 shares at $6.85 per share, 31,588 shares at $6.90, and 82,877 Shares at $8.00 per share since our Offering was qualified. Due to the popularity of the shares and in an effort to maximize shareholder value, we are increasing our share price to $8.20 per share. Effective February 25, 2019, the Board of Directors consented to a 2 to 1 stock split resulting in 6,394,391 Class A shares outstanding. On October 18, 2019, the founders of the Company agreed to a 4 to 1 reverse stock split bringing down the outstanding shares to 2,867,114 shares of Class A Common Stock.

3. The Company currently has no Preferred Stock outstanding.

4. After the commencement of our Offering, all of our Preferred Stock converted into Class A Common Stock. On February 25, 2019, the Company effectuated a 2 for 1 stock split of the outstanding shares. On October 18, 2019, the founders of the Company agreed to a 4 to 1 reverse stock split of their shares. The authorized shares remained the same.

The Company may not be able to sell the Maximum Offering Amount. The Company will conduct one or more closings on a rolling basis as funds are received from investors. Funds tendered by investors will be kept in an account in the Company’s and will be immediately available to the Company. Once a subscription agreement is accepted by the Company, funds are non-refundable.

We are not listed on any trading market or stock exchange, and our ability to list our stock in the future is uncertain. Investors should not assume that the Offered Shares will be listed. A public trading market for the Shares may not develop.

RISK FACTORS

The purchase of the Company's Class A Common Stock involves substantial risks. You should carefully consider the following risk factors in addition to any other risks associated with this investment. The Shares offered by the Company constitute a highly speculative investment and you should be in an economic position to lose your entire investment. The risks listed do not necessarily comprise all those associated with an investment in the Shares and are not set out in any particular order of priority. Additional risks and uncertainties may also have an adverse effect on the Company's business and your investment in the Shares. An investment in the Company may not be suitable for all recipients of this Offering Circular. You are advised to consult an independent professional adviser or attorney who specializes in investments of this kind before making any decision to invest. You should consider carefully whether an investment in the Company is suitable in the light of your personal circumstances and the financial resources available to you.

The discussions and information in this Offering Circular may contain both historical and forward-looking statements. To the extent that the Offering Circular contains forward-looking statements regarding the financial condition, operating results, business prospects, or any other aspect of the Company's business, please be advised that the Company's actual financial condition, operating results, and business performance may differ materially from that projected or estimated by the Company in forward-looking statements. The Company has attempted to identify, in context, certain of the factors it currently believes may cause actual future experience and results may differ from the Company's current expectations.

Before investing, you should carefully read and carefully consider the following risk factors:

Risks Relating to the Company and Its Business

The Company Has Limited Operating History

The Company has a limited operating history and there can be no assurance that the Company's proposed plan of business can be realized in the manner contemplated and, if it cannot be, shareholders may lose all or a substantial part of their investment. There is no guarantee that it will ever realize any significant operating revenues or that its operations will ever be profitable.

The Company Is Dependent Upon Its Management, Founders, Key Personnel and Consultants to Execute the Business Plan, And Many Of Them Will Have Concurrent Responsibilities At Other Companies

The Company's success is heavily dependent upon the continued active participation of the Company's current executive officers as well as other key personnel and consultants. Many of them will have concurrent responsibilities at other entities. Some of the advisors, scientists, consultants and others to whom the Company's ultimate success may be reliant have not signed contracts with the Company and may not ever do so. Loss of the services of one or more of these individuals could have a material adverse effect upon the Company's business, financial condition or results of operations. Further, the Company's success and achievement of the Company's growth plans depend on the Company's ability to recruit, hire, train and retain other highly qualified scientific, technical and managerial personnel. Competition for qualified employees and consultants among companies in the applicable industries is intense, and the loss of any of such persons, or an inability to attract, retain and motivate any additional highly skilled employees and consultants required for the initiation and expansion of the Company's activities, could have a materially adverse effect on it. The inability to attract and retain the necessary personnel, consultants and advisors could have a material adverse effect on the Company's business, financial condition or results of operations.

New chemical entities derived from our Matrix BioHydrogel Program, which is in the early stages of development, may require more time and resources for development, testing and regulatory clearance, and may not result in viable commercial products

Our Matrix BioHydrogel Program is in the early stages of development, involves a novel therapeutic approach and new chemical entities, requires significant further research and development and regulatory approvals and is subject to the risks of failure inherent in the development of products based on innovative approaches. New chemical entities derived from our Matrix BioHydrogel Program are molecules that have not previously been approved and marketed as therapeutics, unlike products used to create candidates for our Drug Delivery Program, as is the case with AnestaGel; we are using bupivacaine, a proven pain relief drug that has been used for many decades in treating pain, and then we apply our formulation expertise and Matrix BioHydrogel technologies to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve in some manner through a new formulation. As a result, the product candidates from our Matrix BioHydrogel Program may face greater risk of unanticipated safety issues or other side-effects, or may not demonstrate efficacy. Further, the regulatory pathway for our new chemical entities may be more demanding.

Also, because our Matrix BioHydrogel Program is in early stages, we have not defined with precision those indications we wish to pursue initially, each of which may have unique challenges. If the first indications pursued do not show positive results, the credibility of any product candidate from this program may be tarnished, even if the molecule might be effective for other indications. Our decisions regarding which indications to pursue may cause us to fail to capitalize on indications that could have given rise to viable commercial products and profitable market opportunities.

Early indications of activity from GLP Pre-clinical (animal) studies of AnestaGel may not predict the results of clinical (human) trials

There can be no assurance that clinical studies will demonstrate the safety or efficacy of AnestaGel in a statistically significant manner. The failure of AnestaGel to show efficacy in Phase 2 or Phase 3 clinical trials would significantly harm our business.

Clinical trial safety results, including for AnestaGel, may not be confirmed

While some clinical trials of our product candidates may show indications of safety and efficacy, there can be no assurance that these results will be confirmed in subsequent clinical trials or provide a sufficient basis for regulatory approval. In addition, side effects observed in clinical trials, or other side effects that appear in later clinical trials, may adversely affect our or our collaborators' ability to obtain regulatory approval or market our product candidates. For example, the reduction in pain intensity on movement of AnestaGel compared to bupivacaine HCl in previous trials may not be repeated in the ongoing AnestaGel trials. There can be no assurance that the additional clinical trial that could be conducted for AnestaGel will be sufficient to obtain FDA approval, and any additional trials would entail added expense and further delay or may preclude product approval, harming our business, prospects and financial condition.

Regulatory action or failure to obtain product approvals could delay or limit development and commercialization of our product candidates and result in failure to achieve anticipated revenues

The manufacture and marketing of our pharmaceutical product candidates and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. We or our third-party collaborators must obtain clearance or approval from applicable regulatory authorities before we or they, as applicable, can perform clinical trials, market or sell our products in development in the United States or abroad. Clinical trials, manufacturing and marketing of products are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. In particular, the FDA rigorously focuses on the safety of drug products at every stage of drug development and commercialization from initial clinical trials to regulatory approval and beyond, and the interpretation of data that may pertain to safety can be subject to the interpretation of individual reviewers within the FDA. These rigorous and potentially evolving standards, that often differ by therapeutic area, may delay and increase the expenses of our development efforts. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators' development and commercialization activities due to safety concerns, in which case our business will be harmed. In addition, the FDA or other foreign regulatory agency may refuse or delay approval of our or our collaborators' drug candidates for failure to collect sufficient clinical or animal safety data, and require us or our collaborators to conduct additional clinical or animal safety studies which may cause lengthy delays and increased costs to our programs.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. These laws and regulations are complex and subject to change. Furthermore, these laws and regulations may be subject to varying interpretations, and we may not be able to predict how an applicable regulatory body or agency may choose to interpret or apply any law or regulation to our pharmaceutical product candidates. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources. We or our third-party collaborators, as applicable, may encounter delays or rejections based upon administrative action or interpretations of current rules and regulations. We or our third-party collaborators, as applicable, may not be able to timely reach agreement with the FDA on our clinical trials or on the required clinical or animal data we or they must collect to continue with our clinical trials or eventually commercialize our product candidates.

We or our third-party collaborators, as applicable, may also encounter delays or rejections based upon additional government regulation from future legislation, administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We or our third-party collaborators, as applicable, may encounter similar delays in foreign countries. Sales of our pharmaceutical product candidates outside the United States are subject to foreign regulatory standards that vary from country to country.

The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We or our third-party collaborators, as applicable, may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify. If we or our third-party collaborators, as applicable, fail to obtain timely clearance or approval for our development products, we or they will not be able to market and sell our pharmaceutical product candidates, which will limit our ability to generate revenue.

We may depend to a large extent on third-party collaborators, and we have limited or no control over the development, sales, distribution and disclosure for our pharmaceutical product candidates which are the subject of third-party collaborative or license agreements

Our performance may depend to a large extent on the ability of third-party collaborators, if we are able to enter into agreements, to successfully develop and obtain approvals for our pharmaceutical product candidates. We hope to enter into agreements with many companies under which we grant such third parties the right to develop, apply for regulatory approval for, market, promote or distribute AnestGel and certain other Matrix BioHydrogel based product candidates, subject to payments to us in the form of product royalties and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these product candidates, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Enforcing any of these agreements in the event of a breach by the other party could require the expenditure of significant resources and consume a significant amount of management time and attention. Our collaborators may also conduct their activities in a manner that is different from the manner we would have chosen, had we been developing such product candidates ourselves. Further, our collaborators may elect not to develop or commercialize product candidates arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these product candidates. If any of these events occur, we may not recognize revenue from the commercialization of our product candidates based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our product candidates. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

Cancellation of collaborations regarding our product candidates may impact our revenues and adversely affect potential economic benefits

Third-party collaboration agreements typically allow the third party to terminate the agreement (or a specific program within an agreement) by providing notice.

Our revenues, if any, may depend on collaboration agreements with other companies. These agreements may subject us to obligations which must be fulfilled and also make our revenues dependent on the performance of such third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenues may decrease. Acquisitions of our collaborators can be disruptive

Our revenues, if any, may be based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities set forth in these agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationships with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to managing our operations. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new product candidates, or can lead to lengthy, expensive litigation or arbitration. From time to time, our licensees may be the subject of an acquisition by another company. Such transactions can lead to turnover of program staff, a review of development programs and strategies by the acquirer, and other events that can disrupt a program, resulting in program delays or discontinuations.

If any of our collaborative agreements were to be terminated or delayed, our anticipated revenues may be reduced or not materialize, and our products in development related to those agreements may not be commercialized.

Our cash flows are likely to differ from our reported revenues

Our revenues, if any, will likely differ from our cash flows from revenue-generating activities. Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and generally recognized on a straight-line basis over the period of our continuing involvement with the third-party collaborator pursuant to the applicable agreement.

Our revenues, if any, may also depend on milestone payments based on achievements by our third-party collaborators. Failure of such collaborators to attain such milestones would result in our not receiving additional revenues

In addition to payments, if any, based on our performance of research and development activities, our revenues may also depend on the attainment of milestones set forth in our collaboration agreements. Such milestones are typically related to development activities or sales accomplishments. While our involvement is necessary to the achievement of development-based milestones, the performance of our third-party collaborators is also required to achieve those milestones. Under our third-party collaborative agreements, our third party collaborators will take the lead in commercialization activities and we are typically not involved in the achievement of sales-based milestones. Therefore, we are even more dependent upon the performance of our third-party collaborators in achieving sales-based milestones. To the extent we and our third-party collaborators do not achieve such development-based milestones or our third-party collaborators do not achieve sales-based milestones, we will not receive the associated revenues, which could harm our financial condition and may cause us to defer or cut-back development activities or forego the exploitation of opportunities in certain geographic territories, any of which could have a material adverse effect on our business.

Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our pharmaceutical product candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal, and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well the collaborators' own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.

We will require and may have difficulty raising needed capital in the future

Our business currently does not generate sufficient revenues to meet our capital requirements and we do not expect that it will do so in the near future. We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our pharmaceutical product candidates. We will require additional funds for these purposes, to establish additional clinical- and commercial-scale manufacturing arrangements and facilities, and to provide for the marketing and distribution of our product candidates. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially harm our business, financial condition and results of operations.
Our actual capital requirements will depend on many factors, including:

- regulatory actions with respect to our product candidates;
- continued progress and cost of our research and development programs;
- the continuation of our collaborative agreements that provide financial funding for our activities;
- success in entering into collaboration agreements and meeting milestones under such agreements;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our pharmaceutical product candidates;
- costs involved in establishing manufacturing capabilities for clinical and commercial quantities of our product candidates;
- competing technological and market developments;
- market acceptance of our product candidates;
- costs for recruiting and retaining employees and consultants; and
- unexpected legal, accounting and other costs and liabilities related to our business.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate collaborators or other sources, which may be dilutive to existing stockholders and may cause the price of our common stock to decline. In addition, in the event that additional funds are obtained through arrangements with collaborators or other sources, we may have to relinquish rights to some of our technologies or pharmaceutical product candidates that we would otherwise seek to develop or commercialize ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in delays in generating potential future product revenue.

We and any third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical product candidates and components to support the clinical and commercial requirements of our collaborators and ourselves at an acceptable cost or in compliance with applicable government regulations, and we have limited manufacturing experience

We or any third-party collaborators to whom we have assigned such responsibility must manufacture our pharmaceutical product candidates and components in clinical and commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. The manufacturing processes associated with our product candidates are complex. We have not yet completed development of the manufacturing process for any product candidates or components, including AnestaGel and our other Matrix BioHydrogel-based drug candidates. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our product candidates, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our product candidates. We have also committed to manufacture and supply product candidates or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a product candidate or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that product candidate or we may be in breach of our supply obligations to our third-party collaborators.

Our development and licensing partner, Lifecore Biomedical is a multi-disciplinary site that we contract with to manufacture our AnestaGel and Matrix BioHydrogel. This is currently completed on an as needed basis. We anticipate that in the future, should the Phase 1 Clinical Study, and Efficacy Study prove to be successful, that Lifecore would continue to manufacture the Product. If we experience delays or technical difficulties in scaling up the manufacturing of our product candidates, it could result in delays or added cost in our development programs. We have not manufactured commercial quantities of any of our product candidates. In the future, we intend to develop additional manufacturing capabilities for our product candidates and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers.

If we and our third-party collaborators, where relevant, are unable to manufacture our pharmaceutical product candidates or components in a timely manner or at an acceptable cost, quality or performance level, and are unable to attain and maintain compliance with applicable regulations, the clinical trials and the commercial sale of our product candidates and those of our third-party collaborators could be delayed. Additionally, we may need to alter our facility design or manufacturing processes, install additional equipment or do additional construction or testing in order to meet regulatory requirements, optimize the production process, increase efficiencies or production capacity or for other reasons, which may result in additional cost to us or delay production of product needed for the clinical trials and commercial launch of our product candidates and those of our third-party collaborators.

If we or our third-party collaborators cannot manufacture our pharmaceutical product candidates or components in time to meet the clinical or commercial requirements of our collaborators or ourselves or at an acceptable cost, our operating results will be harmed.

Failure to comply with ongoing governmental regulations for our pharmaceutical product candidates could materially harm our business in the future

Marketing or promoting a drug is subject to very strict controls. Furthermore, clearance or approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and requirements that we update our regulatory filings. Later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our product candidates, which in turn would materially harm our business, financial condition and results of operations:

- failure to obtain or maintain requisite governmental approvals;
- failure to obtain approvals for clinically intended uses of our pharmaceutical product candidates under development; or
- FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

Manufacturers of drugs must comply with the applicable FDA good manufacturing practice regulations, which include production design controls, testing, quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Compliance with current good manufacturing practices regulations is difficult and costly. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used for the commercial manufacture of our development products. We and/or our present or future suppliers and distributors may be unable to comply with the applicable good manufacturing practice regulations and other FDA regulatory requirements. We have not been subject to a good manufacturing regulation inspection by the FDA relating to our product candidates. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our product candidates we or they manufacture, the FDA may refuse or withdraw marketing clearance or require product recall, which may cause interruptions or delays in the manufacture and sale of our product candidates.

We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability

We have incurred operating losses since our inception in 2014 and, as of December 31, 2018, had an accumulated deficit of approximately $1.3 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales, and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed product candidates, obtain the required regulatory clearances, and manufacture and market our proposed product candidates. Development of pharmaceutical product candidates is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology for use in our product candidates. The license fees for these technologies or rights would increase the costs of our product candidates.

We do not anticipate meaningful revenues to derive from the commercialization and marketing of our product candidates in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

We may develop our own sales force and commercial group to market future products but we have limited sales and marketing experience with respect to pharmaceuticals and may not be able to do so effectively

We may choose to develop our own sales force and commercial group to market products that we may develop in the future. Developing a sales force and commercial group will require substantial expenditures and the hiring of qualified personnel. We have limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales personnel. If we are not able to put in place an appropriate sales force and commercial group for AnestaGel, we may not be able to effectively launch the product. We may not be able to effectively sell our product candidates, if approved, and our failure to do so could limit or materially harm our business.

We and our third-party collaborators may not sell our product candidates effectively

We and any third-party collaborators compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts and those of our third-party collaborators may be unable to compete successfully against these other companies. We and our third-party collaborators, if relevant, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, if relevant, may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our product candidates;
- cease operations with little or no notice to us;
- offer, design, manufacture or promote competing product lines;
- fail to maintain adequate inventory and thereby restrict use of our product candidates; or
- build up inventory in excess of demand thereby limiting future purchases of our product candidates resulting in significant quarter-to-quarter variability in our sales.

The failure of us or any third-party collaborators to effectively develop, gain regulatory approval for, sell, manufacture and market our product candidates will hurt our business, prospects and financial results.

We will rely heavily on third parties to support development, clinical testing and manufacturing of our product candidates

We will rely on third-party contract research organizations, consultants, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our product candidates. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our product candidates. These third parties may not execute their responsibilities and tasks competently in compliance with applicable laws and regulations or in a timely fashion. We rely on third-parties to manufacture or perform manufacturing steps relating to our product candidates or components. We anticipate that we will continue to rely on these and other third-party contractors to support development, clinical testing, and manufacturing of our product candidates. Failure of these contractors to provide the required services in a competent or timely manner or on reasonable commercial terms could materially delay the development and approval of our development products, increase our expenses and materially harm our business, financial condition and results of operations.

Key components of our product candidates are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs

Certain components and drug substances used in our product candidates, including AnestaGel, and our other Matrix BioHydrogel-based drug candidates, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

- delays associated with redesigning a pharmaceutical product candidate due to a failure to obtain a single source component;
- an inability to obtain an adequate supply of required components; and
- reduced control over pricing, quality and delivery time.

We have supply agreements in place for certain components of our pharmaceutical product candidates, but do not have in place long term supply agreements with respect to all of the components of any of our product candidates. Therefore the supply of a particular component could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required components or drugs from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source components could cause us to seek alternative sources of supply or manufacture these components internally. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary components. If the supply of any components for our product candidates is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete clinical trials and obtain approval for commercialization and marketing of our product candidates, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation.

If we are unable to adequately protect, maintain or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us

Our ability to commercially exploit our products will depend significantly on our ability to obtain and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others.

As of December 31, 2018, we have licensed over 20 unexpired issued U.S. patents and over 23 unexpired issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have a pending U.S. patent application and over numerous foreign applications pending in Europe, Australia, Japan, Canada and other countries.

There can be no assurance that the pending patent applications will be granted. The granted claims in the U.S. include both composition of matter and method of treatment claims. There can be no assurance that the pending patent applications will be granted.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

The patent laws of the U.S. have recently undergone changes through court decisions which may have significant impact on us and our industry. Decisions of the U.S. Supreme Court and other courts with respect to the standards of patentability, enforceability, availability of injunctive relief and damages may make it more difficult for us to procure, maintain and enforce patents. In addition, the America Invents Act was signed into law in September 2011, which among other changes to the U.S. patent laws, changes patent priority from “first to invent” to “first to file,” implements a post-grant opposition system for patents and provides a prior user defense to infringement. These judicial and legislative changes have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us will be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference, derivation, post-grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may be unsuccessful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

Our future collaboration agreements may depend on our intellectual property

We expect to be party to collaborative agreements with pharmaceutical companies. Potential third-party collaborators may have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business. To the extent that our agreements call for future royalties to be paid conditional on our having patents covering the royalty-bearing subject matter, the decision by the Supreme Court in the case of *MedImmune v. Genentech* could encourage our licensees to challenge the validity of our patents and thereby seek to avoid future royalty obligations without losing the benefit of their license. Should they be successful in such a challenge, our ability to collect future royalties could be substantially diminished.

We may be sued by third parties claiming that our product candidates infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents

We or our potential collaborators may be exposed to future litigation by third parties based on claims that our product candidates or activities infringe the intellectual property rights of others or that we or our collaborators have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us or our collaborators, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. We also may not have sufficient funds to litigate against parties with substantially greater resources. In addition, pursuant to our collaborative agreements, we have provided our collaborators with the right, under specified circumstances, to defend against any claims of infringement of the third party intellectual property rights, and such collaborators may not defend against such claims adequately or in the manner that we would do ourselves. Intellectual property litigation or claims could force us or our collaborators to do one or more of the following, any of which could harm our business or financial results:

- cease selling, incorporating or using any of our pharmaceutical product candidates that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our product candidates, which would be costly and time-consuming.

Technologies and businesses which we acquire or license may be difficult to integrate, disrupt our business, dilute stockholder value or divert management attention

We may acquire technologies, products or businesses to broaden the scope of our existing and planned product lines and technologies. Future acquisitions expose us to:

- increased costs associated with the acquisition and operation of the new businesses or technologies and the management of geographically dispersed operations;
- the risks associated with the assimilation of new technologies, operations, sites and personnel;
- the diversion of resources from our existing business and technologies;
- the inability to generate revenues to offset associated acquisition costs;
- the requirement to maintain uniform standards, controls, and procedures; and
- the impairment of relationships with employees and customers or third-party collaborators as a result of any integration of new management personnel.

Acquisitions may also result in the issuance of dilutive equity securities, the incurrence or assumption of debt or additional expenses associated with the amortization of acquired intangible assets or potential businesses. Acquisitions may not generate any additional revenue or provide any benefit to our business.

Some of our pharmaceutical product candidates contain controlled substances, the making, use, sale, importation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies

Some of our product candidates currently under development contain, and our products in the future may contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation and distribution. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our product candidates containing controlled substances. In particular, among other things, there is a risk that these regulations may interfere with the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

Write-offs related to the impairment of long-lived assets, inventories and other non-cash charges, as well as stock-based compensation expenses may adversely impact or delay our profitability

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill and other intangible assets. We will continue to incur non-cash charges related to amortization of other intangible assets. We are required to perform periodic impairment reviews of our goodwill at least annually. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact or delay our profitability.

The valuation of inventory requires us to estimate the value of inventory that may become expired prior to use. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval of a product by the necessary regulatory bodies, changes in product development timelines, or other information that suggests that the inventory will not be saleable.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives

Our cash and cash equivalents will be maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments could consist primarily of readily marketable debt securities with original maturities of greater than 90 days from the date of purchase but remaining maturities of less than one year from the balance sheet date. Our long-term investments could consist primarily of readily marketable debt securities with maturities in one year or beyond from the balance sheet date. While, as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments, no assurance can be given that deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents, short-term investments or long-term investments or our ability to meet our financing objectives.

We depend upon key personnel who may terminate their employment with us at any time, and we may need to hire additional qualified personnel

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources.

We may not successfully manage our company through varying business cycles

Our success will depend on properly sizing our company through growth and contraction cycles caused in part by changing business conditions, which places a significant strain on our management and on our administrative, operational and financial resources. To manage through such cycles, we must expand or contract our facilities, our operational, financial and management systems and our personnel. If we were unable to manage growth and contractions effectively our business would be harmed.

Our business involves environmental risks and risks related to handling regulated substances

In connection with our research and development activities and our manufacture of materials and pharmaceutical product candidates, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the use, generation and disposal of hazardous materials, including but not limited to certain hazardous chemicals, solvents, agents and biohazardous materials. The extent of our use, generation and disposal of such substances has increased substantially since we started manufacturing and selling biodegradable polymers. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances generated by us, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Risks Related To Our Industry

The market for our pharmaceutical product candidates is rapidly changing and competitive, and new products or technologies developed by others could impair our ability to grow our business and remain competitive

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our product candidates under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery. Our Matrix BioHydrogel based products, including AnestaGel, if cleared by the FDA and other governing bodies, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, anti-psychotics, stimulants, implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue Pharma, AbbVie, Janssen, Medtronic, Endo, AstraZeneca, Pernix Therapeutics, Tricumed, Halyard Health, Cumberland Pharmaceuticals, Pacira, Acorda Therapeutics, Mallinckrodt, Shire, Johnson & Johnson, Eli Lilly, Pfizer, Novartis and others. Purdue Pharma, Sandoz, Actavis, Collegium Pharmaceutical, Pfizer, Elite Pharmaceuticals, Intellipharmaceutics, Egalet, Teva Pharmaceuticals and others have also announced regulatory approval or development plans for abuse deterrent opioid products. Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira, Immune Pharmaceuticals, Innocoll, Nektar, Kimberly-Clark, Acorda Therapeutics, Flamel, Alexza, Mallinckrodt, Hospira, Pfizer, Cumberland Pharmaceuticals, Egalet, Acura, Elite Pharmaceuticals, Phosphagenics, Intellipharmaceutics, Collegium Pharmaceutical, Heron Therapeutics and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

We are engaged in the development of novel therapeutic technologies. Our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our product candidates even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices which will be competitive with our product candidates. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our product candidates to receive widespread acceptance if commercialized.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. These regulations include:

- the Federal Healthcare Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, and which as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, state laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our collaborators or potential collaborators. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which is intended to contain or reduce the costs of medical products and services. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs";
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- addresses new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- mandates a further shift in the burden of Medicaid payments to the states.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, automatic reductions to several government programs were enacted during "sequestration." These reductions included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates once approved or additional pricing pressures.

We could be exposed to significant product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage

The testing, manufacture, marketing and sale of our product candidates involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our product candidates, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our product candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our product candidates.

Acceptance of our pharmaceutical product candidates in the marketplace is uncertain, and failure to achieve market acceptance will delay our ability to generate or grow revenues

Our future financial performance will depend upon the successful introduction and customer acceptance of our products in research and development, including AnestaGel and other Matrix BioHydrogel-based candidates. Even if approved for marketing, our product candidates may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products, including oral medication, transdermal drug delivery products such as drug patches, injectable therapeutics, or external or implantable drug delivery products; and
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval, commercialize and market our future products when planned and achieve market acceptance, we will not achieve anticipated revenues.

If users of our products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

The successful commercialization of our product candidates will depend in part on the extent to which appropriate reimbursement levels for the cost of our product candidates and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors often limit payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

If we or our third-party collaborators are unable to train physicians to use our pharmaceutical product candidates to treat patients' diseases or medical conditions, we may incur delays in market acceptance of our products

Broad use of our product candidates will require extensive training of numerous physicians on the proper and safe use of our product candidates. The time required to begin and complete training of physicians could delay introduction of our products and adversely affect market acceptance of our products. We or third parties selling our product candidates may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our product candidates. Any delay in training would materially delay the demand for our product candidates and harm our business and financial results. In addition, we may expend significant funds towards such training before any orders are placed for our products, which would increase our expenses and harm our financial results.

Our Independent Auditor Firm Has Expressed In Its Report To Our 2017 Audited Financial Statements A Substantial Doubt About Our Ability To Continue As A Going Concern.

We have not yet entered into the commercialization stage of our products and therefore commercialization is uncertain and expected to require substantial expenditures. We have not yet generated sufficient revenues from our operations to fund our activities, and are therefore dependent upon external sources for financing our operations. There is a risk that we will be unable to obtain necessary financing to continue our operations on terms acceptable to us or at all. As a result, our independent auditor firm has expressed in its auditors' report on the financial statements a substantial doubt regarding our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. If we cannot continue as a going concern, our stockholders may lose their entire investment in the Class A Common Stock.

Our Operating Plan Relies In Large Part Upon Assumptions And Analyses Developed By The Company. If These Assumptions Or Analyses Prove To Be Incorrect, The Company's Actual Operating Results May Be Materially Different From Our Forecasted Results

Whether actual operating results and business developments will be consistent with the Company's expectations and assumptions as reflected in its forecast depends on a number of factors, many of which are outside the Company's control, including, but not limited to:

- whether the Company can obtain sufficient capital to sustain and grow its business
- our ability to manage the Company's growth
- whether the Company can manage relationships with key vendors and advertisers
- demand for the Company's products and services
- the timing and costs of new and existing marketing and promotional efforts
- competition
- the Company's ability to retain existing key management, to integrate recent hires and to attract, retain and motivate qualified personnel
- the overall strength and stability of domestic and international economies

Unfavorable changes in any of these or other factors, most of which are beyond the Company's control, could materially and adversely affect its business, results of operations and financial condition.

To Date, The Company Has Had Operating Losses And Does Not Expect To Be Initially Profitable For At Least The Foreseeable Future, And Cannot Accurately Predict When It Might Become Profitable

The Company has been operating at a loss since the Company's inception, and the Company expects to continue to incur losses for the foreseeable future. Further, the Company may not be able to generate significant revenues in the future. In addition, the Company expects to incur substantial operating expenses in order to fund the expansion of the Company's business. As a result, The Company expects to continue to experience substantial negative cash flow for at least the foreseeable future and cannot predict when, or even if, the Company might become profitable.

Risks Relating to This Offering and Investment

The Company May Undertake Additional Equity or Debt Financing That May Dilute The Shares In This Offering

The Company may undertake further equity or debt financing which may be dilutive to existing shareholders, including you, or result in an issuance of securities whose rights, preferences and privileges are senior to those of existing shareholders, including you, and also reducing the value of Shares subscribed for under this Offering.

An Investment In The Shares Is Speculative And There Can Be No Assurance Of Any Return On Any Such Investment

An investment in the Company's Shares is speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in the Company, including the risk of losing their entire investment.

The Shares Are Offered On A "Best Efforts" Basis And The Company May Not Raise The Maximum Amount Being Offered

Since the Company is offering the Shares on a "best efforts" basis, there is no assurance that the Company will sell enough Shares to meet its capital needs. If you purchase Shares in this Offering, you will do so without any assurance that the Company will raise enough money to satisfy the full USE OF PROCEEDS TO COMPANY which the Company has outlined in this Offering Circular or to meet the Company's working capital needs.

If The Total Maximum Offering Is Not Raised, It May Increase The Amount Of Long-Term Debt Or The Amount Of Additional Equity It Needs To Raise

There is no assurance that the maximum amount of Shares in this offering will be sold. If the Total Maximum Offering amount is not sold, we may need to incur additional debt or raise additional equity in order to finance our operations. Increasing the amount of debt will increase our debt service obligations and make less cash available for distribution to our shareholders. Increasing the amount of additional equity that we will have to seek in the future will further dilute those investors participating in this Offering.

We Have Not Paid Dividends In The Past And Do Not Expect To Pay Dividends In The Foreseeable Future, So Any Return On Investment May Be Limited To The Value Of Our Shares

We have never paid cash dividends on our Shares and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends on our Shares will depend on earnings, financial condition and other business and economic factors affecting it at such time that management may consider relevant. If we do not pay dividends, our Shares may be less valuable because a return on your investment will only occur if its stock price appreciates.

The Company May Not Be Able To Obtain Additional Financing

Even if the Company is successful in selling the maximum number of Shares in the Offering, the Company may require additional funds to continue and grow its business. The Company may not be able to obtain additional financing as needed, on acceptable terms, or at all, which would force the Company to delay its plans for growth and implementation of its strategy which could seriously harm its business, financial condition and results of operations. If the Company needs additional funds, the Company may seek to obtain them primarily through additional equity or debt financings. Those additional financings could result in dilution to the Company's current shareholders and to you if you invest in this Offering.

An Investment in the Company's Shares Could Result In A Loss of Your Entire Investment

An investment in the Company's Shares offered in this Offering involves a high degree of risk and you should not purchase the Shares if you cannot afford the loss of your entire investment. You may not be able to liquidate your investment for any reason in the near future.

There Is No Assurance The Company Will Be Able To Pay Distributions To Shareholders

While the Company may choose to pay distributions at some point in the future to its shareholders, there can be no assurance that cash flow and profits will allow such distributions to be made.

There is No Public Trading Market for the Company's Shares

At present, there is no active trading market for the Company's securities and the Company cannot assure that a trading market will develop. The Company's Class A Common Stock has no trading symbol. In order to obtain a trading symbol and authorization to have the Company's securities trade publicly, the Company must file an application on Form 211 with, and receive the approval by, the Financial Industry Regulatory Authority ("FINRA") of which there is no assurance, before active trading of the Company's securities could commence. If the Company's securities ever publicly trade, they may be relegated to the OTC Pink Sheets. The OTC Pink Sheets provide significantly less liquidity than the NASD's automated quotation system, or NASDAQ Stock Market. Prices for securities traded solely on the Pink Sheets may be difficult to obtain and holders of the Shares and the Company's securities may be unable to resell their securities at or near their original price or at any price. In any event, except to the extent that investors' Shares may be registered on a Form S-1 Registration Statement with the Securities and Exchange Commission in the future, there is absolutely no assurance that Shares could be sold under Rule 144 or otherwise until the Company becomes a current public reporting company with the Securities and Exchange Commission and otherwise is current in the Company's business, financial and management information reporting, and applicable holding periods have been satisfied.

Sales Of Our Shares By Insiders Under Rule 144 Or Otherwise Could Reduce The Price Of Our Shares, If A Trading Market Should Develop

Certain officers, directors and/or other insiders may hold shares in the Company and may be able to sell their stock in a trading market if one should develop. The availability for sale of substantial amounts of stock by officers, directors and/or other insiders could reduce prevailing market prices for our securities in any trading market that may develop.

Should Our Securities Become Quoted On A Public Market, Sales Of A Substantial Number Of Shares Of Our Type Of Stock May Cause The Price Of Our Type Of Stock To Decline

Should a market develop and our shareholders sell substantial amounts of our Shares in the public market, Shares sold may cause the price to decrease below the current offering price. These sales may also make it more difficult for us to sell equity or equity-related securities at a time and price that we deem reasonable or appropriate.

Because The Company Does Not Have An Audit Or Compensation Committee, Shareholders Will Have To Rely On Our Directors To Perform These Functions

The Company does not have an audit or compensation committee comprised of independent directors or any audit or compensation committee. The board of directors performs these functions as a whole. No members of the board of directors are independent directors. Thus, there is a potential conflict in that board members who are also part of management will participate in discussions concerning management compensation and audit issues that may affect management decisions.

The Company Has Made Assumptions In Its Projections and In Forward-Looking Statements That May Not Be Accurate

The discussions and information in this Offering Circular may contain both historical and "forward-looking statements" which can be identified by the use of forward-looking terminology including the terms "believes," "anticipates," "continues," "expects," "intends," "may," "will," "would," "should," or, in each case, their negative or other variations or comparable terminology. You should not place undue reliance on forward-looking statements. These forward-looking statements include matters that are not historical facts. Forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward-looking statements contained in this Offering Circular, based on past trends or activities, should not be taken as a representation that such trends or activities will continue in the future. To the extent that the Offering Circular contains forward-looking statements regarding the financial condition, operating results, business prospects, or any other aspect of the Company's business, please be advised that the Company's actual financial condition, operating results, and business performance may differ materially from that projected or estimated by the Company. The Company has attempted to identify, in context, certain of the factors it currently believes may cause actual future experience and results to differ from its current expectations. The differences may be caused by a variety of factors, including but not limited to adverse economic conditions, lack of market acceptance, reduction of consumer demand, unexpected costs and operating deficits, lower sales and revenues than forecast, default on leases or other indebtedness, loss of suppliers, loss of supply, loss of distribution and service contracts, price increases for capital, supplies and materials, inadequate capital, inability to raise capital or financing, failure to obtain customers, loss of customers and failure to obtain new customers, the risk of litigation and administrative proceedings involving the Company or its employees, loss of government licenses and permits or failure to obtain them, higher than anticipated labor costs, the possible acquisition of new businesses or products that result in operating losses or that do not perform as anticipated, resulting in unanticipated losses, the possible fluctuation and volatility of the Company's operating results and financial condition, adverse publicity and news coverage, inability to carry out marketing and sales plans, loss of key executives, changes in interest rates, inflationary factors, and other specific risks that may be referred to in this Offering Circular or in other reports issued by us or by third-party publishers.

Investors In This Offering Will Experience Immediate And Substantial Dilution

Due to our significant accumulated deficit, investors in this offering will suffer immediate and substantial dilution of $6.49 per share or approximately 79.41% of the offering price of the shares if the Total Maximum Offering is sold. Further, if all of the shares offered hereby are sold, investors in this offering will own approximately 12.22% of the then outstanding shares of common stock, but will have paid approximately 100% of the total consideration for our outstanding shares. See “Dilution.”

The Company Has Significant Discretion Over The Net Proceeds Of This Offering

The Company has significant discretion over the net proceeds of this Offering. As is the case with any business, particularly one without a proven business model, it should be expected that certain expenses unforeseeable to management at this juncture will arise in the future. There can be no assurance that management’s use of proceeds generated through this offering will prove optimal or translate into revenue or profitability for the Company. Investors are urged to consult with their attorneys, accountants and personal investment advisors prior to making any decision to invest in the Company.

The Offering Price For The Type Of Stock Has Been Determined By The Company

The price at which the Shares are being offered has been arbitrarily determined by the Company. There is no relationship between the offering price and our assets, book value, net worth, or any other economic or recognized criteria of value. Rather, the price of the Shares was derived as a result of internal decisions based upon various factors including prevailing market conditions, our future prospects and our capital structure. These prices do not necessarily accurately reflect the actual value of the Shares or the price that may be realized upon disposition of the Shares.

You Should Be Aware Of The Long-Term Nature Of This Investment

There is not now, and likely will not be in the near future, a public market, for the Shares. Because the Shares have not been registered under the Securities Act or under the securities laws of any state or non-United States jurisdiction, the Shares may have certain transfer restrictions. It is not currently contemplated that registration under the Securities Act or other securities laws will be effected. Limitations on the transfer of the Shares may also adversely affect the price that you might be able to obtain for the Shares in a private sale. You should be aware of the long-term nature of your investment in the Company. You will be required to represent that you are purchasing the Securities for your own account, for investment purposes and not with a view to resale or distribution thereof.

Neither The Offering Nor The Securities Have Been Registered Under Federal Or State Securities Laws, Leading To An Absence Of Certain Regulation Applicable To The Company

The Company also has relied on exemptions provided by Regulation A of the JOBS Act from securities registration requirements under applicable state and federal securities laws. Investors in the Company, therefore, will not receive any of the benefits that such registration would otherwise provide. Prospective investors must therefore assess the adequacy of disclosure and the fairness of the terms of this Offering on their own or in conjunction with their personal advisors.

The Shares In This Offering Have No Protective Provisions.

The Shares in this Offering have no protective provisions. As such, you will not be afforded protection, by any provision of the Shares or as a Shareholder in the event of a transaction that may adversely affect you, including a reorganization, restructuring, merger or other similar transaction involving the Company. If there is a “liquidation event” or “change of control” the Shares being offered do not provide you with any protection. In addition, there are no provisions attached to the Shares in the Offering that would permit you to require the Company to repurchase the Shares in the event of a takeover, recapitalization or similar transaction.

The Shares In This Offering Are Subject to A Right of First Refusal Under Certain Circumstances.

The Shares in this Offering are subject to a right of first refusal. Until the Shares are listed on an exchange and made available for trading, no Shareholder shall sell, assign, pledge or in any manner transfer any of the Shares of the corporation or any right or interest therein, whether voluntarily or by operation of law, or by gift or otherwise, without first giving written notice thereof to the Company, who then shall have the right to purchase the Shares from the Shareholder, subject to certain limitations. For a complete description of this right of first refusal, see " Securities Being Offered " below and the Company's Bylaws.

You Will Not Have A Vote Or Influence On The Management Of The Company

Substantially all decisions with respect to the management of the Company will be made exclusively by the officers, directors, managers or employees of the Company. You will have a very limited ability, if at all, to vote on issues of Company management and will not have the right or power to take part in the management of the Company and will not be represented on the board of directors or by managers of the Company. Accordingly, no person should purchase Shares unless he or she is willing to entrust all aspects of management to the Company.

No Guarantee of Return on Investment

There is no assurance that you will realize a return on your investment or that you will not lose your entire investment. For this reason, you should read the Form 1-A, Offering Circular and all exhibits and referenced materials carefully and should consult with your own attorney and business advisor prior to making any investment decision.

IN ADDITION TO THE RISKS LISTED ABOVE, BUSINESSES ARE OFTEN SUBJECT TO RISKS NOT FORESEEN OR FULLY APPRECIATED BY THE MANAGEMENT. IT IS NOT POSSIBLE TO FORESEE ALL RISKS THAT MAY AFFECT THE COMPANY. MOREOVER, THE COMPANY CANNOT PREDICT WHETHER THE COMPANY WILL SUCCESSFULLY EFFECTUATE THE COMPANY'S CURRENT BUSINESS PLAN. EACH PROSPECTIVE PURCHASER IS ENCOURAGED TO CAREFULLY ANALYZE THE RISKS AND MERITS OF AN INVESTMENT IN THE SECURITIES AND SHOULD TAKE INTO CONSIDERATION WHEN MAKING SUCH ANALYSIS, AMONG OTHER FACTORS, THE RISK FACTORS DISCUSSED ABOVE.

USE OF PROCEEDS TO COMPANY

The Use of Proceeds is an estimate based on the Company's current business plan. We may find it necessary or advisable to reallocate portions of the net proceeds reserved for one category to another, or to add additional categories, and we will have broad discretion in doing so. For example, if our research and development activities need to be bolstered beyond our initial estimates we may allocate additional resources by reallocating proceeds from other categories such as marketing for the purposes of research and development. We do not believe we will reallocate from our fixed costs such as equipment or rent. The Company believes that funding at nearly any level could result in significant progress being made toward gaining a Phase 1 Clinical Study. The Company believes it is nearing the time to enter clinical (human) studies, after one more pre-clinical (animal) study to confirm certain blood levels of the drug bupivacaine during the first 24-24 hours of use of AnestaGel. Upon completion of that GLP Pre-clinical study, the company anticipates discussing the results of all the pre-clinical and bench testing and making an application f to begin a Phase 1 Clinical Study. This would examine the safety of AnestaGel, and the Company would be applying for an Investigational New Drug ("IND") with the United States Food and Drug Administration ("FDA"), which it has not yet done. The Company has completed the capital acquisition of its laboratory equipment in previous financings, and further laboratory expenses are directly related to compounding products. The Company can slow down or accelerate product development, pre-clinical studies, and clinical studies based on available funds. Nearly all expenses are variable, and employees are willing to delay compensation from time to time, if need be. The Company estimates that net proceeds of only $900,000 could allow for just over two years of operations and adequate time to seek additional, most likely, private funding or a commercial partner. In the event the Company raises $1 million it believes it could be able to complete GLP studies required for Phase 1 Clinical Studies conduct a Pre-IND meeting with the FDA, and complete the protocol for the Phase I Clinical Studies. The Company would need to seek additional funding from other sources to complete the manufacturing for, and the Clinical Studies, adding 12-24 months to the current 24-month timeline. If the Company were to raise $3 million it believes it could be financed to complete all of the above and finish manufacturing for Phase 1 Clinical Studies. The Company would need to seek additional funding from other sources to complete the Clinical Studies, adding 12 months to the current 24-month timeline. If the Company raises $5 million it believes it could complete all of the above and the Phase 1 Clinical Study, including analysis of the results, submission for peer review. Timelines would not be affected. If the Company raises $7.5 million it believes it could complete all of the above, and a commercial manufacturing program. Timelines would not be affected. If the Company raises $10 million it believes could complete all of the above and an 80-person clinical study for Efficacy via the 505(b)2 pathway.

The maximum gross proceeds from the sale of the Shares in this Offering are $10,000,003.20. The net proceeds from the offering, assuming it is fully subscribed, are expected to be approximately $9,215,088 after the payment of offering costs including broker-dealer and selling commissions, but before printing, mailing, marketing, legal and accounting costs, and other compliance and professional fees that may be incurred. The estimate of the budget for offering costs is an estimate only and the actual offering costs may differ from those expected by management.

A portion of the proceeds from this Offering may ultimately be used to compensate or otherwise make payments to officers or directors of the Company. The officers and directors of the Company may be paid salaries and receive benefits that are commensurate with similar companies, and a portion of the proceeds may be used to pay these ongoing business expenses.

The Company reserves the right to change the use of proceeds set out herein based on the needs of the ongoing business of the Company and the discretion of the Company's management. The Company may reallocate the estimated use of proceeds among the various categories or for other uses if management deems such a reallocation to be appropriate. Until sufficient funds are raised by the Company to sufficiently fund research activities, management may utilize some or all of the funds from this Offering for further capital raising efforts, rather than as set out in this Use of Proceeds section of the Offering Circular.

The Company has attempted to identify, in context, certain of the factors it currently believes may cause actual future experience and results to differ from its current expectations. The differences may be caused by a variety of factors, including but not limited to adverse economic conditions, lack of market acceptance, reduction of consumer demand, unexpected costs and operating deficits, lower sales and revenues than forecast, default on leases or other indebtedness, loss of suppliers, loss of supply, loss of distribution and service contracts, price increases for capital, supplies and materials, inadequate capital, inability to raise capital or financing, failure to obtain customers, loss of customers and failure to obtain new customers, the risk of litigation and administrative proceedings involving the Company or its employees, loss of government licenses and permits or failure to obtain them, higher than anticipated labor costs, the possible acquisition of new businesses or products that result in operating losses or that do not perform as anticipated, resulting in unanticipated losses, the possible fluctuation and volatility of the Company's operating results and financial condition, adverse publicity and news coverage, inability to carry out marketing and sales plans, loss of key executives, changes in interest rates, inflationary factors, and other specific risks that may be referred to in this Offering Circular or in other reports issued by us or by third-party publishers.

Category	**100%**	**75%**	**50%**	**25%**	**10%**
Gross Proceeds	$ 10,000,003	$ 7,500,007	$ 5,000,005	$ 2,500,002	$ 1,000,001
Offering Expenses(1)	$ 700,001	$ 525,000	$ 350,000	$ 175,000	$ 100,000
Selling Commissions & Fees(2)	$ 84,914	$ 59,914	$ 34,914	$ 9,914	$ 0
Net Proceeds	**$ 9,215,094**	**$ 6,915,092**	**$ 4,615,090**	**$ 2,315,088**	**$ 900,001**
Compensation and Benefits	$ 2,835,000	$ 1,725,085	$ 826,086	$ 420,086	$ 230,000
Travel	$ 100,560	$ 100,560	$ 61,485	$ 23,760	$ 23,760
Communications and Utilities	$ 38,460	$ 38,460	$ 28,920	$ 7,980	$ 7,980
Office Supplies and Support	$ 7,200	$ 7,200	$ 7,200	$ 2,400	$ 2,400
Laboratory Supplies and Support	$ 1,866,025	$ 1,628,425	$ 1,299,842	$ 590,000	$ 390,000
Facility	$ 50,666	$ 31,333	$ 31,333	$ 12,000	$ 12,000
Marketing & Promotion	$ 0	$ 0	$ 0	$ 0	$ 0
Corporate Items	$ 523,166	$ 471,046	$ 462,243	$ 208,862	$ 66,000
Regulatory Fees and Consultants	$ 3,262,982	$ 2,837,983	$ 1,872,981	$ 1,025,000	$ 157,861
Legal and Accounting	$ 120,000	$ 75,000	$ 25,000	$ 25,000	$ 10,000
Contingency	$ 411,029	$ 0	$ 0	$ 0	$ 0
Total Use of Net Proceeds	**$ 9,215,088**	**$ 6,915,092**	**$ 4,615,090**	**$ 2,315,088**	**$ 900,001**
Total Use of Gross Proceeds	**$ 10,000,003**	**$ 7,500,007**	**$ 5,000,005**	**$ 2,500,002**	**$ 1,000,001**
	($0)	($0)	($0)	$ 0	$ 0

1. Total expenditures for offering proceeds are anticipated to be $700,000, These direct and indirect expenditures include primarily SEC legal, preliminary legal and accounting, auditing services, marketing expenses, digital advertising expenses, filing fees, and other similar expenses related to the Regulation A offering. The Company has agreed to pay FundAthena, Inc., doing business as Manhattan Street Capital ("Manhattan Street Capital") for its services in hosting the offering of the shares on its online platform. This compensation consists of: (i) $25 per investor in cash paid when such investor deposits funds into escrow; with a minimum payment of $5,000 per month while the offering is live to investors (ii) a warrant to purchase that number of shares of Common Stock determined by multiplying $25 by the total number of investors in this offering and dividing by the price at which our common stock is sold in this offering, The warrants will have an exercise price equal to the price at which our common stock is sold in this offering Manhattan Street Capital does not directly solicit or communicate with investors with respect to offerings posted on its site, although it does advertise the existence of its platform, which may include identifying a broad selection of issuers listed on the platform. Warrants will be delivered to Manhattan Street Capital promptly upon the close of the offering. If the offering does not complete successfully for any reason, the warrants earned will be promptly delivered to Manhattan Street Capital. Payments of cash and warrants to Manhattan Street Capital are not contingent upon the success of the offering.

2. The Company has Engaged Sageworks Capital, LLC to assist in the sale of the shares remaining under the Form 1-A at a rate of 1.0%. Further, the Company has agreed to pay a fee of $10,000 to Sageworks for due diligence as well as $2,000 for fees. These costs have already been accounted for in "Offering Expenses."

3. Expenses related to the salaries associated with research and development work on our products.

4. Expense related to supplies to pursue research and development, animal studies, and FDA testing.

5. Expenses related to the FDA approval of our products.

DETERMINATION OF OFFERING PRICE

This Offering is a self-underwritten offering, which means that it does not involve the participation of an underwriter to market, distribute or sell the common stock offered under this offering. Our Offering Price is arbitrary with no relation to value of the company. The Company has engaged Manhattan Street Capital, LLC to perform administrative and technology related functions in connection with this offering, but not for underwriting or placement agent services.

If all the Shares in this offering are fully subscribed and sold, the Shares offered herein will constitute approximately 29.38% of the total Shares of stock of the Company.

DILUTION

The term “dilution” refers to the reduction (as a percentage of the aggregate Shares outstanding) that occurs for any given share of stock when additional Shares are issued. If all the Shares in this offering are fully subscribed and sold, the remaining Shares offered herein will constitute approximately 12.22% of the total Shares of stock of the Company. The Company anticipates that subsequent to this offering the Company may require additional capital and such capital may take the form of Class A Common Stock, other stock or securities or debt convertible into stock. Such future fund raising will further dilute the percentage ownership of the Shares sold herein in the Company. The dilution table below is based on the Company’s balance sheet dated June 30, 2018.

If you invest in our Class A Common Stock, your interest will be diluted immediately to the extent of the difference between the offering price per share of our Class A Common Stock and the pro forma net tangible book value per share of our Class A Common Stock after this offering.

The following chart includes the conversion of the Preferred Stock.

	100%	75%	50%	25%	10%
Net Tangible Assets	$ 10,879,462.00	$ 8,602,857.00	$ 6,326,252.00	$ 4,049,647.00	$ 2,683,684.00
Offering Expenses	$ 784,915.05	$ 584,914.86	$ 384,914.67	$ 184,914.48	$ 100,000.00
Net Tangible	$ 10,094,546.95	$ 8,017,942.14	$ 5,941,337.33	$ 3,864,732.52	$ 2,583,684.00
New Shares	817,117.00	612,838	408,559	204,279	81,712
Total Shares	6,684,231	6,479,952	6,275,673	6,071,393	5,948,826
Previous Value	$ 0.30220	$ 0.30220	$ 0.30220	$ 0.30220	$ 0.30220
Book Value per Share	$ 1.5102	$ 1.2373	$ 0.9467	$ 0.6365	$ 0.4343
Increase to Old Shareholders	$ 1.2080	$ 0.9351	$ 0.6445	$ 0.3343	$ 0.1321
Change in Value	$ 6.4898	$ 6.7627	$ 7.0533	$ 7.3635	$ 7.5657
Percentage Dilution	79.14%	82.47%	86.02%	89.80%	92.26%
Percentage of Outstanding	12.22%	9.46%	6.51%	3.36%	1.37%

PLAN OF DISTRIBUTION

We are offering a Total Maximum Offering of up to $10,000,003 in Shares of our Class A Common Stock. The offering is being conducted on a best-efforts basis without any minimum number of shares or amount of proceeds required to be sold. There is no minimum subscription amount required (other than a per investor minimum purchase) to distribute funds to the Company. All subscribers will be instructed by the Company or its agents to transfer funds by wire, check, or ACH transfer directly to the bank account established for this Offering or deliver checks made payable to "InSitu Biologics, Inc." The Company may terminate the offering at any time for any reason at its sole discretion and may extend the Offering past the Closing Date if the absolutely discretion of the Company and in accordance with the rules and provisions of Regulation A of the JOBS Act.

The Company has agreed to pay Sageworks Capital, LLC a 1.0% commission for the sale of the securities herein. The Company has also agreed to pay a due diligence fee of $10,000 to Sageworks as well as $2,000 in filing fees.

None of the Shares being sold in this offering are being sold by existing securities holders. All of the Class A Common Stock was authorized as of June 15, 2017 and issued by the Company.

After the Offering Statement has been qualified by the Securities and Exchange Commission (the "SEC"), the Company will accept tenders of funds to purchase the Shares. The Company does not intend to use an escrow agent as this is a "best efforts" offering and funds will be available immediately to the Company for use.

The Offering Circular will be furnished to prospective investors in this offering via download 24 hours a day, 7 days a week on the Manhattan Street Capital website; www.manhattanstreetcapital.com.

We will also use our existing website, www.InSitu Biologics.com, to provide notification of the Offering. The Offering Circular will also be furnished to prospective investors via download 24 hours per day, 7 days per week on the www.InSitu Biologics.com website.

You will be required to complete a subscription agreement in order to invest. The subscription agreement includes a representation to the effect that, if you are not an "accredited investor" as defined under securities law, you are investing an amount that does not exceed the greater of 10% of your annual income or 10% of your net worth, as described in the subscription agreement.

The Company has engaged Manhattan Street Capital to perform the following administrative and technology related functions in connection with this offering, but not for underwriting or placement agent services. Manhattan Street Capital will contract the services of a third party, FundAmerica, for the purpose of payment processing and storage of confidential investor data.

1. Accept investor data from potential investors on behalf of the Company;

2. Reject investors that do not pass anti-money laundering ("AML") or that do not provide the required information;

3. Process Subscription Agreements and reject investors that do not complete subscription Agreements;

4. Reject investments from potential investors who do not meet requirements for permitted investment limits for investors pursuant to Regulation A, Tier 2;

6. Reject investments from potential investors with inconsistent, incorrect or otherwise flagged (e.g. for underage or AML reasons) subscriptions;

8. Oversee transmittal by FundAmerica of data to the company's transfer agent in the form of book-entry data for maintaining the company's responsibilities for managing investors (investor relationship management, aka "IRM") and record keeping;

9. Receive and transmit investor data to FundAmerica to store investor details and data confidentially and not disclose to any third party except as required by regulators, by law or in our performance under this Agreement (e.g. as needed for AML); and

10. The Company has agreed to pay FundAthena, Inc., doing business as Manhattan Street Capital ("Manhattan Street Capital") for its services in hosting the offering of the shares on its online platform. This compensation consists of: (i) $25 per investor in cash paid when such investor deposits funds into escrow; minimum $5,000 per month while the offering is live to investors (ii) a warrant to purchase that number of shares of Common Stock determined by multiplying $25 by the total number of investors in this offering and dividing by the price at which our common stock is sold in this offering, The warrants will have an exercise price equal to the price at which our common stock is sold in this offering. Manhattan Street Capital does not directly solicit or communicate with investors with respect to offerings posted on its site, although it does advertise the existence of its platform, which may include identifying a broad selection of issuers listed on the platform. Warrants will be delivered to Manhattan Street Capital promptly upon the close of the offering. If the offering does not complete successfully for any reason, the warrants earned will be promptly delivered to Manhattan Street Capital. Payments of cash and warrants to Manhattan Street Capital are not contingent upon the success of the offering.

Funds will be deposited in an account at US Bank, NA. Payments are processed via Fundamerica U.S. Bank, N.A. and will be made immediately available to the Company. No escrow account will be utilized. If a subscription is rejected, funds will be returned to subscribers within thirty days of such rejection without deduction or interest. Upon acceptance by us of a subscription, a confirmation of such acceptance will be sent to the subscriber by the Company. Manhattan Street Capital has not investigated the desirability or advisability of investment in the shares nor approved, endorsed or passed upon the merits of purchasing the Shares. Manhattan Street Capital is not participating as an underwriter and under no circumstance will it solicit any investment in the Company, recommend the Company's securities or provide investment advice to any prospective investor, or make any securities recommendations to investors. Manhattan Street Capital is not distributing any securities offering prospectuses or making any oral representations concerning the securities offering prospectus or the securities offering. Based upon Manhattan Street Capital's anticipated limited role in this offering, it has not and will not conduct extensive due diligence of this securities offering and no investor should rely on Manhattan Street Capital's involvement in this offering as any basis for a belief that it has done extensive due diligence. Manhattan Street Capital does not expressly or impliedly affirm the completeness or accuracy of the Form 1-A and/or Offering Circular presented to investors by the Company. All inquiries regarding this offering should be made directly to the Company.

This offering will commence on the qualification of this Offering Circular, as determined by the Securities and Exchange Commission and continue indefinitely until all of the offered Shares are sold or the Offering is terminated in the Company's sole discretion. Funds received from investors will be counted towards the Offering only if the form of payment, such as a check, clears the banking system and represents immediately available funds held by us prior to the termination of the subscription period, or prior to the termination of the extended subscription period if extended by the Company, and only for investors that pass the Anti Money Laundering check and that complete their Subscription Agreement.

If you decide to subscribe for any Class A Common Stock in this offering, you must deliver a check, certified funds or another acceptable form of payment for acceptance or rejection. The minimum investment amount for a single investor is 300 shares of Class A Common Stock in the cumulative principal amount of $2,460.00. All subscription checks should be sent to PrimeTrust and made payable to InSitu Biologics. If a subscription is rejected, all funds will be returned to subscribers within thirty days of such rejection without deduction or interest. Upon acceptance by the company of a subscription, a confirmation of such acceptance will be sent to the investor.

The Company maintains the right to accept or reject subscriptions in whole or in part, for any reason or for no reason. All monies from rejected subscriptions will be returned by the Company to the investor, without interest or deductions.

This is an offering made under "Tier 2" of Regulation A, and the shares will not be listed on a registered national securities exchange upon qualification. Therefore, the shares will be sold only to a person if the aggregate purchase price paid by such person is no more than 10% of the greater of such person's annual income or net worth, not including the value of his primary residence, as calculated under Rule 501 of Regulation D promulgated under Section 4(a)(2) of the Securities Act of 1933, as amended. In the case of sales to fiduciary accounts (Keogh Plans, Individual Retirement Accounts (IRAs) and Qualified Pension/Profit Sharing Plans or Trusts), the above suitability standards must be met by the fiduciary account, the beneficiary of the fiduciary account, or by the donor who directly or indirectly supplies the funds for the purchase of the shares. Investor suitability standards in certain states may be higher than those described in the Form 1-A and/or Offering Circular. These standards represent minimum suitability requirements for prospective investors, and the satisfaction of such standards does not necessarily mean that an investment in the Company is suitable for such persons. Different rules apply to accredited investors.

Each investor must represent in writing that he/she/it meets the applicable requirements set forth above and in the Subscription Agreement, including, among other things, that (i) he/she/it is purchasing the shares for his/her/its own account and (ii) he/she/it has such knowledge and experience in financial and business matters that he/she/it is capable of evaluating without outside assistance the merits and risks of investing in the shares, or he/she/it and his/her/its purchaser representative together have such knowledge and experience that they are capable of evaluating the merits and risks of investing in the shares. Broker-dealers and other persons participating in the offering must make a reasonable inquiry in order to verify an investor's suitability for an investment in the company. Transferees of the shares will be required to meet the above suitability standards.

The shares may not be offered, sold, transferred, or delivered, directly or indirectly, to any person who (i) is named on the list of "specially designated nationals" or "blocked persons" maintained by the U.S. Office of Foreign Assets Control ("OFAC") at www.ustreas.gov/offices/enforcement/ofac/sdn or as otherwise published from time to time, (ii) an agency of the government of a Sanctioned Country, (iii) an organization controlled by a Sanctioned Country, or (iv) is a person residing in a Sanctioned Country, to the extent subject to a sanctions program administered by OFAC. A "Sanctioned Country" means a country subject to a sanctions program identified on the list maintained by OFAC and available at www.ustreas.gov/offices/enforcement/ofac/sdn or as otherwise published from time to time. Furthermore, the shares may not be offered, sold, transferred, or delivered, directly or indirectly, to any person who (i) has more than fifteen percent (15%) of its assets in Sanctioned Countries or (ii) derives more than fifteen percent (15%) of its operating income from investments in, or transactions with, sanctioned persons or Sanctioned Countries.

The sale of other securities of the same class as those to be offered for the period of distribution will be limited and restricted to those sold through this Offering. Because the Shares being sold are not publicly or otherwise traded, the market for the securities offered is presently stabilized.

DESCRIPTION OF THE BUSINESS

InSitu Biologics™, LLC was formed in 2014. In November 2017, InSitu Biologics, LLC was converted into a Delaware Corporation under the name, InSitu Biologics, Inc. InSitu Biologics, Inc. ("Company" or "InSitu") researches, develops, tests and manufactures implantable time release products composed of its proprietary tunable, bio-polymeric hydrogel, Matrix™ BioHydrogel. InSitu has developed AnestaGel™, a patented drug-delivery product based on technology originally created by scientists at the Cleveland Clinic. AnestaGel has been developed for the perioperative pain management market. AnestaGel has unique features including being completely biocompatible, pH neutral, site-specific placement and tunable.

The Company is completing its product development and pre-clinical testing, which will then bring us to the next steps in our business: small scale production of AnestaGel for human use, and the clinical (human) study of AnestaGel for people having certain surgeries. The Company believes it is nearing the time to enter clinical (human) studies, after one more pre-clinical (animal) study to confirm certain blood levels of the drug bupivacaine during the first 24-24 hours of use of AnestaGel. Upon completion of that GLP Pre-clinical study, the company anticipates discussing the results of all the pre-clinical and bench testing and making an application f to begin a Phase 1 Clinical Study. This would examine the safety of AnestaGel, and the Company would be applying for an Investigational New Drug ("IND") with the United States Food and Drug Administration ("FDA"), which it has not yet done. If the Company is successful in proving safety in the Phase 1 Study, the Company believes it would be required to then perform an efficacy study of approximately 80 subjects. The Company has been advised that under the 505(b)2 pathway, that if the efficacy study is successful, it could then be in position to apply for commercial clearance of AnestaGel.

The 505(b)(2) new drug application (NDA) is one of three U.S. Food and Drug Administration (FDA) drug approval pathways and represents an appealing regulatory strategy for many clients. The pathway was created by the Hatch-Waxman Amendments of 1984, with 505(b)(2) referring to a section of the Federal Food, Drug, and Cosmetic Act. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved drug; 505(b)(2) gives the FDA express permission to rely on data not developed by the NDA applicant.

A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant.

Exparel from Pacira was approved on the basis of a 505(b)(2) NDA that relied, in part, on FDA's previous findings of safety for Marcaine. The eventual AnestaGel 505(b)(2) NDA will establish efficacy and safety via a showing of comparable bioavailability to Marcaine (and possibly Exparel) along with nonclinical and clinical studies needed to ensure that differences between Marcaine and the listed drug(s) do not adversely affect safety and effectiveness.

Summary

AnestaGel represents a potentially transformational technology in the perioperative pain control market. Its tunable, programmable nature, and the ability to modify its form factor to meet the need of nearly every surgery has not been contemplated for a targeted pain molecule.

- Matrix BioHydrogel is a tunable, biocompatible, and pH neutral platform. It allows AnestaGel to provide target site-specific, non-migratory placement, a flexible and high dose drug-load reservoir capacity, and tunable and a predictable pharmacological effect.
- The characteristics of Matrix BioHydrogel permit AnestaGel to be manufactured in a variety of form factors, allowing the product to be designed on an application-specific basis and to suit physician and hospital preference.
- Based on InSitu's MULTIPLE preclinical (animal) feasibility studies, the data suggests that AnestaGel may deliver faster and longer lasting pain relief than liposome based technologies.
- InSitu's process development and licensing partner is Lifecore Biomedical.

AnestaGel has only been tested in the pre-clinical (animal) model. However, based on that data AnestaGel's financial opportunity is as potentially disruptive as the technology. InSitu believes AnestaGel is a unique, novel product for pain control that after further pre-clinical studies, and studies performed under the rules of the United States Food and Drug Administration (FDA), AnestaGel could be a safe, efficacious, and manufacturable product alternative to opioids used in controlling surgical pain.

AnestaGel

AnestaGel uses a novel approach to deliver sustained-released analgesics into the target tissue. The AnestaGel product uses InSitu's proprietary Matrix BioHydrogel platform, which is based on a patent portfolio and proof of concept for a biocompatible hydrogel created by the Cleveland Clinic Foundation (CCF) beginning in the early 2000's.

All of the components of Matrix BioHydrogel are made in the body or can be metabolized by the body. InSitu's ability to accurately tune the physical form and rate of absorption to the targeted length of use for a particular tissue is highly desirable. InSitu believes that AnestaGel, composed of the Company's Matrix BioHydrogel technology and any of the "caine" family of pharmaceuticals, could be commercialized to have therapeutic application in many different surgical patient populations that suffer from pain.

AnestaGel offers a new approach to perioperative pain management that is opioid-sparing, tunable, biocompatible, target site-specific, and flexible.

The Company believes that AnestaGel can be used in three distinct markets for perioperative pain management:

- Surgical Site / Perioperative: There are an estimated 90 million surgical procedures in the US, resulting in $10B of drugs / devices being sold in the US.
- Peripheral Nerve Block: This occurs in the majority of surgical procedures, and is a product market that is estimated to grow to $20B by the year 2025
- Epidural: There are an estimated 2.5M procedures in the US and a product market estimated at $1B

Sources: U.S. Department of Health & Human Services; Pacira Pharmaceuticals; National Center for Biotechnology Information (NCBI)

Unique Characteristics and Advantages

AnestaGel has the following characteristics and advantages:

- Matrix BioHydrogel is a tunable, biocompatible, and pH neutral platform. It allows AnestaGel to provide target site-specific, non-migratory placement, a flexible and high dose drug-load reservoir capacity, and tunable and a predictable pharmacological effect.
- The characteristics of Matrix BioHydrogel permit AnestaGel to be manufactured in a variety of form factors, allowing the product to be designed on an application-specific basis and to suit physician and hospital preference.
- The data from InSitu's preclinical GLP and feasibility studies suggests that AnestaGel may deliver faster and longer lasting pain relief than liposome based technologies.
- InSitu's process development and licensing partner is a Lifecore Biomedical, a wholly owned subsidiary of Landec Corporation. Lifecore is a contract development and manufacturing company and has developed numerous products related to hyaluaronic acid and valuable methods for making those related products.

Sizable Product Market Need

AnestaGel applications can address untapped, rapid growth opportunities and large existing patient populations, based on InSitu's market research. InSitu believes that AnestaGel has many applications because it can be delivered in various forms and viscosities and may be long lasting for perioperative applications.

Rapid Growth Opportunities

- There is tremendous demand for non-opioid alternatives for perioperative pain management.
- AnestaGel provides a technical platform to develop products that could be used for multiple procedures performed in Ambulatory Surgery Centers (ASC's).

Acceptance and Interest

- Medical Community: Biomaterial injections into synovial joints for temporary therapeutic treatments are currently considered routine therapy. Expanding the use of this class of materials has been contemplated for years.
- Patients: Therapeutic patient driven choice is expected to become an increasingly important factor. AnestaGel technology is easily understood and a natural biomaterial. The growing patient awareness and interest in potentially dangerous biomaterials in the pain management market will potentially promote the acceptance and use of AnestaGel in the future.

History

The original patent portfolio and proof of concept for this biocompatible hydrogel was created by the Cleveland Clinic Foundation ("CCF") in the early 2000's. The Company has licensed a number of patents from this portfolio. Please see Exhibit 6 "License Agreement".

Since then, extensive time, talent and money has been devoted to the development and research of the technology behind AnestaGel by InSitu. InSitu Biologic founders, James Segermark ("Jim") and William Taylor ("Bill"), became involved with the CCF technology, in 2007 and 2006. The original focus and work concentrated on using a form of the hydrogel for bulking applications.

Taylor and Segermark completed their work on these projects around 2009. Jim and Bill continued to develop numerous hydrogels for various medical applications. In early 2014, after completing elution studies, they formed InSitu Biologics to begin making and testing AnestaGel. InSitu procured an exclusive, royalty free license. InSitu has since transitioned the biohydrogel bulking agent to a far more sophisticated, implantable delivery vehicle for the newly created bio-absorbable subcutaneous regional pain control market.

On August 31, 2019, Mr. Segermark resigned as CEO and Mr. Kevin Bassett accepted a position as CEO and President of the Company.

The Market

Operative Pain Management

Operative pain management is a vast market that remains dominated by opioids. It is an area that hospitals, doctors and patients continue to find inadequate, despite inroads of new options.

According to The New Guidelines Released for Postoperative Pain Management, by Dr. Laurie Barclay and Pauline Anderson, acute postoperative pain is common, occurring in more than 80% of patients, with approximately 75% of these having moderate, severe, or extreme pain. Postoperative pain relief is inadequate in more than half of patients, which can negatively affect quality of life, function, and functional recovery, as well as increasing the risks for postsurgical complications and persistent postsurgical pain.

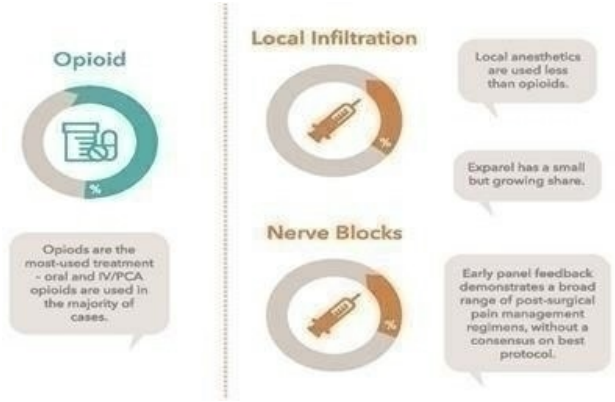
Numerous studies and research reinforces the fact that postoperative pain relief remains inadequate and there is a major need for non-opioid alternatives. A sample of the research findings are presented below:

- 73% of inpatient and 57% of outpatient surgeries have moderate to extreme pain postoperatively, despite opioid use by nearly 90% of patients. Pain continues to be undermanaged, according to, Habib AS, Miller research by Gan TJ TE, White W, Apfelbaum JL. Results from a US national survey, Curr Med Res Opin. 2014
- Experiencing postoperative pain was the most common concern (59%) of patients. Almost 25% of patients who received pain medications experienced adverse effects.
- In the United States, more than 73 million surgeries are performed annually, and up to 75% of patients experience pain after surgery. Managing patient pain after surgery often remains top of mind for hospitals despite inroads in new technology, therapies, and processes that have helped lower pain experiences, according to Elizabeth A Reid, Content Manager, Guidepoint; a leading global research services firm.
- **There are about 46 million inpatient and 53 million outpatient surgeries performed in the United States each year that require drugs for post-operative pain, and over half of these patients still experience inadequate pain relief, according to a report by Cara Therapeutics on the acute pain market.**
- Acute postoperative pain is a serious problem for many patients. Nearly 50% of postoperative patients have moderate pain, and more than one-third suffer severe pain. There are serious consequences to unrelieved pain, both physically and psychologically, according to PAINWeek.
- Inadequately managed and undertreated postoperative pain remains a major clinical, economic and social challenge. The current standard of care for the treatment of post-operative pain relies heavily on the use of opioids supplemented by other classes of pain medications, the combination of which is known as multi-modal pain therapy.
- Given the negative side effects and costs associated with opioid use in particular, there is increasing focus from hospitals, payors and regulators on treatments that reduce opioid use in the treatment of postoperative pain
- Stronger, Longer, and Opioid-sparing Postoperative Pain Management Approaches Are Urgently Needed
- Untapped Opportunity: Long-acting Anesthetics Currently Make Up Only 5% of the Postoperative Pain Relief Market
- According to Post-Surgical Pain Management TRACKER data from January 2015, “opioids were the most-used treatments, with oral and IV/PCA opioids used in the majority of cases. But early feedback from the TRACKER’s panel demonstrates a broad range of post-surgical pain management regimens, with various user preferences. Data shows that while opioids are leading the pack, local anesthetic infiltration and nerve blocks are popular and gaining market share. Guidepoint’s Post-Surgical Pain Management TRACKER also tracks the usage of *EXPAREL*, a single-dose, non-opioid, long-acting local anesthetic currently indicated for injection into tissues at the site of surgery, and finds that usage is lower than short-acting local anesthetics although the drug has been used in many cases and is growing share in its largest segment of use, the orthopedic setting.”
- With more than 12 months of treatment data collected, Guidepoint’s Post-Surgical Pain Management TRACKER shows a slow and steady trend of physicians exploring and moving to newer non-opioid therapies, such as *EXPAREL*, and pumps.
- Although 2015 saw a slight decline in opioid treatment share, TRACKER data finds that opioids are still used by the majority (90-95 percent) of post-operative arthroplasty patients.

The Opioid Challenge

“Annually, more than 70 million postsurgical patients receive opioids, and research shows one in 15 will go on to long-term use, indicating that the surgical setting has become an inadvertent gateway to the overall societal epidemic....the best way for hospitals to take immediate action is to implement strategies to minimize preventable opioid exposure,” according to Dr. Scott Sigman, orthopedic surgeon and team physician for the U.S. Ski Jump Team. “States Move to Control How Painkillers Are Prescribed.” New York Times, March 2016.

“Opioids present several potential problems, including side effects such as nausea and vomiting, post-operative ileus, respiratory depression, urinary retention, constipation and the potential for long-term dependence,” according to a report by Frost & Sullivan in 2014, *Every Patient’s Pain is Personal.* Although opioids prove to be an effective treatment for pain management, the drawbacks include the increased risk of fall-related injuries and potential abuse and addiction. As a result, many doctors are turning to emerging alternatives, including new formulations of local anesthetics and elastomeric pumps. *EXPAREL* has detailed its commitment to “providing patients with long-acting, non-opioid analgesic options”. Halyard continues to conduct studies on how its products reduce opioid consumption. Future adoption of these therapies could impact usage of other modalities, according to Guidepost. In the U. S. there is a 55% increase in length of hospital stay due to opioid related AEs; according to Kessler ER, Shah M, Gruschkus SK, Raju A. Pharmacotherapy, 2013.Given the negative side effects and costs associated with opioid use, there is increasing focus from hospitals, payors and regulators on treatments that reduce opioid use in the treatment of postoperative pain.



Addressing the Opioid Epidemic Continues to Gain Attention

The issues associated with opioid addiction continue to garner major focus, which heightens the attention and importance of the development of safer, more effective products for pain management. Following the lead of the National Institutes of Health (NIH), the United States Surgeon General weighed in on this topic in a letter sent to all physicians in August 2016. While much of the focus is on patients in chronic pain, the need for a more effective, longer-lasting product for post-operative pain management is critical, and represents a significant positive behind the early commercial acceptance and success of FDA cleared EXPAREL, and in the development of superior alternatives such as AnestaGel.

UNITED STATES SURGEON GENERAL
Vivek H. Murthy, M.D., M.B.A.

August 2016

Dear Colleague,

I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I travel, I see communities devastated by opioid overdoses. I meet families too ashamed to seek treatment for addiction. And I will never forget my own patient whose opioid use disorder began with a course of morphine after a routine procedure.

It is important to recognize that we arrived at this place on a path paved with good intentions. Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.

The results have been devastating. Since 1999, opioid overdose deaths have quadrupled and opioid prescriptions have increased markedly – almost enough for every adult in America to have a bottle of pills. Yet the amount of pain reported by Americans has not changed. Now, nearly two million people in America have a prescription opioid use disorder, contributing to increased heroin use and the spread of HIV and hepatitis C.

I know solving this problem will not be easy. We often struggle to balance reducing our patients' pain with increasing their risk of opioid addiction. But, as clinicians, we have the unique power to help end this epidemic. As cynical as times may seem, the public still looks to our profession for hope during difficult moments. This is one of those times.

That is why I am asking you to pledge your commitment to turn the tide on the opioid crisis. Please take the pledge at www.TurnTheTideRx.org. Together, we will build a national movement of clinicians to do three things.

First, we will educate ourselves to treat pain safely and effectively. A good place to start is the enclosed pocket card with the CDC Opioid Prescribing Guideline. Second, we will screen our patients for opioid use disorder and provide or connect them with evidence-based treatment. Third, we can shape how the rest of the country sees addiction by talking about and treating it as a chronic illness, not a moral failing.

Years from now, I want us to look back and know that, in the face of a crisis that threatened our nation, it was our profession that stepped up and led the way. I know we can succeed because health care is more than an occupation to us. It is a calling rooted in empathy, science, and service to humanity. These values unite us. They remain our greatest strength.

Thank you for your leadership.

Vivek Murthy

Animal Health Business Opportunity

InSitu Biologics has refined its sustained release analgesic product to the point that it can now be delivered through a small gauge needle without plugging the needle. This was repeatedly proven in pre-clinical and bench testing. Additionally, the formulation was shown to have an analgesic effect for 72-110 hours in rodents and swine. The Company has performed more testing to confirm the presence of bupivacaine in the bloodstream, and those tests confirmed significant, non-toxic levels of pain reducing medication still present in the bloodstream at 96 hours.

This development will allow InSitu to pursue potential partners with whom to enter the rapidly expanding Animal Health Market, and specifically, the Therapeutic Pets and Therapeutic Equine Segments. The American Pets Product Association (APPA) estimates that the Therapeutic Pet Market, which consists of cats and dogs, is worth $70 billion in 2018. The APPA estimates that the Therapeutic Equine Market is worth over $3 billion in 2018. The Company believe that its sustained release product for the Animal Health Market, known as "AniGel™", could be used in the following procedures:

ANIMAL HEALTH BUSINESS OPPORTUNITY TABLE - SUSTAINED RELEASE ANALGESIC

CANINE PROCEDURES 90,000,000 dogs	ANNUAL VOLUME	DOSE PRICE	Annual Canine Market Opportunity
Neuter	15,000,000	$ 75	1,125,000,000
cataract	14,784	$ 125	1,848,000
hip	3,360	$ 125	420,000
knee	3,360	$ 125	420,000
back	3,360	$ 125	420,000
gastroplexy	3,360	$ 125	420,000
organ (all)	3,360	$ 125	420,000
exploratory	3,360	$ 125	420,000
mouth	3,360	$ 125	420,000
eye	3,360	$ 125	420,000
thyroid	3,360	$ 125	420,000
		$ 125	420,000

FELINE PROCEDURES 94,000,000 cats	ANNUAL VOLUME	DOSE PRICE	Annual Market Opportunity
Spay	15,000,000	$ 70	1,050,000,000
hip			
knee			
back			
gastroplexy			
organ (all)			
exploratory			
mouth			
eye			
thyroid			

EQUINE PROCEDURES 6,000,000 horses	ANNUAL VOLUME	DOSE PRICE	Annual Market Opportunity
Regenerative Therapy	20,000	300	6,000,000
Colic			
Athroscopy			
laparoscopy			
eye			
lacerations			
wounds			
ceasarean sections			
general			
air way			

These large markets are extremely attractive for AniGel, as the dose is relatively small and the effect is long lasting. This makes for a potentially very profitable product. The pathway is very clear at the FDA, and Pacira has licensed its product, Nocita, to Aratara Theraputics, Inc., providing for a baseline of expectations with regard to financial terms for licensing as InSitu goes forward. The Animal Health Market is made up of over 110,000 veterinarians, and over 4,000 hospitals that can treat horses.

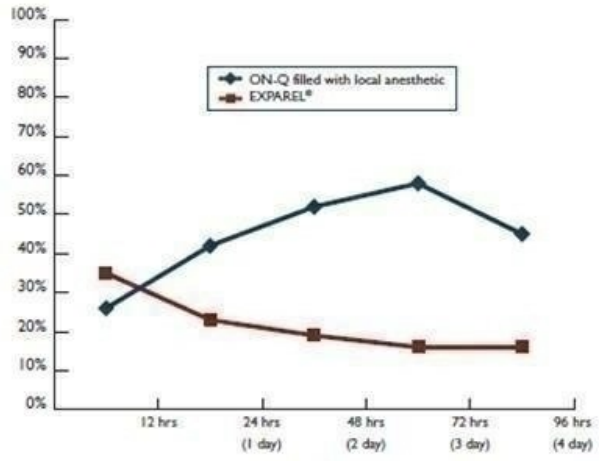
License Agreement

The Company entered into a license agreement with Lifecore Biomedical, LLC ("Lifecore") on November 14, 2014, in connection with certain patents whereby Lifecore granted the Company an exclusive worldwide license, including the right to grant further sublicenses to develop, use, import, export, distribute, market, promote, offer for sale and sell Products. Lifecore retains the right to manufacture and supply to Company and all sublicensees any and all Products developed under the License Agreement. The license agreement has an initial term of 5 years with the Company having to option to renew the agreement if certain regulatory, clinical or sales milestones are met and if the Company pays a renewal fee in the low six figures for each renewal(s). Notwithstanding any renewal, the license agreement will expire at the last to expire valid patent claim of the last to expire licensed patent. Each party may terminate if the other party materially breaches the agreement, subject to notice and opportunities to cure. We may terminate the license agreement at any time on 60 days' notice. Similarly, if the Company were to sublicense a product to a third party that is developed under the licensed patents, the Company would pay Lifecore a sublicense fee in the mid six figures for each product that is sublicensed.

Competition

EXPAREL (bupivacaine liposome injectable suspension) by Pacira Pharmaceuticals, Inc. is a direct competitor to the AnestaGel product. Currently EXPAREL dominates the market for non-opioid products used for postsurgical pain control. EXPAREL is a non-opioid local analgesic indicated for administration into the surgical site to produce postsurgical analgesia. EXPAREL combines bupivacaine with the DepoFoam® drug delivery platform to provide postsurgical pain control with a single intraoperative infiltration. EXPAREL's revenues exceeded $230 million in 2015. Expaerel is an FDA approved and commercially available drug.

Which Pain Management Approach Provides Better Pain Relief at Specific Time Points (Anesthesiologists' Clinical Perspective)



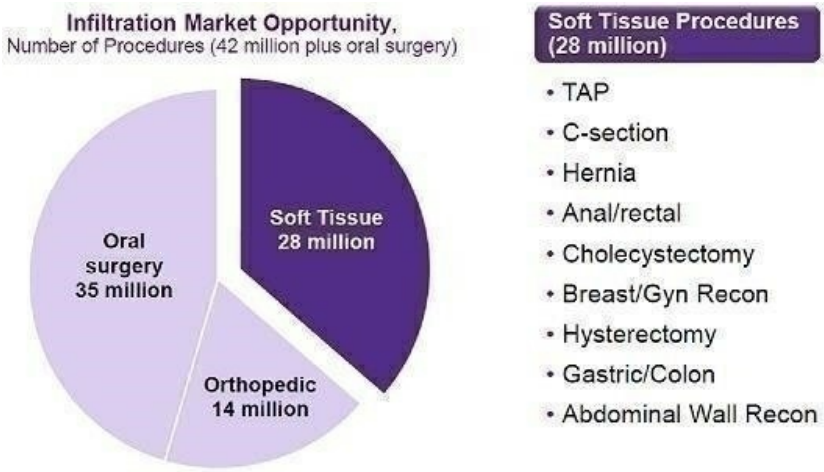
Source: Frost & Sullivan

Unlike the claim of up to 72 hours of pain control marketed by Pacira, anesthesiologist respondents stated that when EXPAREL was used without any adjunctive medications, it provided, on average, only 25 hours of pain relief in their clinical experience. Yet, according to Frost & Sullivan's research, clinicians expect that almost half of major surgery patients will have severely disabling pain beyond 25 hours.

EXPAREL's own clinical data is focused on bunionectomy and hemorrhoidectomy cases, where the clinicians surveyed reported that pain is lower in comparison to major surgery at that 25-hour threshold. Frost & Sullivan's research found that 85% of applications of the drug reported in this survey were neither of those two surgeries.

Relying on EXPAREL as a primary method of post-operative pain relief for major surgical cases runs the risk of under-treating pain later in the critical recovery period. The duration of actual pain relief the two products provide is a significant difference between the products. EXPAREL's claims to provide "up to 72 hours of pain control" are not supported by clinical perspective of participants surveyed or in independent research. The FDA's medical review for EXPARELreported; "In the clinical trials described in the medical review, the duration of EXPAREL's analgesic effect appears to be no more than 24 hours and not longer than that of encapsulated bupivacaine HCl,"Buvanendran A, Fiala J, Patel KA, Golden AD, Moric M, Kroin JS. The incidence and severity of postoperative pain following inpatient surgery. Pain Med. 2015;16(12):2277-2283.

Soft Tissue Market Opportunity



Source: Pacira Pharmaceuticals Corporate Presentation

Orthopedic Market Opportunity

Source: Pacira Pharmaceuticals Corporate Presentation

There are a number of companies that are in various stages of development with new options for post-operative, non-opioid pain management, including (but not limited to) the following:

- Xaracoll - developing a collagen matrix with bupivacaine for postoperative pain management
- Regeneron Pharmaceuticals developing Fasinumab
- Innocoll, with its bupivicaine collagen sponge
- Heron Therapeutics and its HTX-011 product, a mix of bupivacaine and meloxicam for post-operative pain.

Intellectual Property & Patent Portfolio

The materials and AnestaGel applications are supported by a strong patent portfolio consisting of over 20 issued patents (primarily the Calabro patents through The Cleveland Clinic Foundation), and numerous published, pending, and filed and patents. InSitu's manufacturing and development Trade Secrets are aligned with the patent portfolio and maximize InSitu's core competencies across many medical platforms. In general terms, patents 6,982,298, 7,465,766 and 8,207,262 are foundation patents. These explain the chemistry of the hydrogel and introduce basic applications for the hydrogel. Patents 8,138,265, 8,080,260 and 8,410,180 are application specific, but will become foundational patents in the future as InSitu expands IP to include tissue engineering, delivery of hydrogel, and materials/cells to target sites and ways to manipulate the formulation specifically. The Company's existing patents primarily relate to:

- Crosslinking technology and variations using multiple biopolymer backbones
- Tunability of gel to create multiple physical forms
- Drug delivery in numerous applications
- Manufacturing Capabilities
- Significantly developed, proprietary methods

Title	Inventors	Country	Application No.	Date Filed	Status	Focus	License Status
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Richard A. Gross, Aniq B.Darr	Czech Republic	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Richard A. Gross, Aniq B.Darr	Europe	04701177.0	1/9/2004	Published Annuity due: 01/09/2017	Synthetic macromolecular network generally; Methods of making and hydrogel so-made	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	Europe	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	France	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	Germany	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed

Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	United Kingdom	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	Hong Kong	07109551.5	9/3/2007	Published - Annuity due 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material (Extension from EP1)	Licensed (via European application)
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	Italy	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Richard A. Gross, Aniq B.Darr	United States	60/439,201	1/10/2003	Expired	Broad macromolecular network generally; T-HA hydrogels	Licensed through correspondi ng utility patents claiming priority
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	Sweden	05773274.5	7/8/2005	Issued as Pat No. 1773943 Annuity due: 07/08/2017	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Richard A. Gross, Aniq B.Darr	United States	10/753,779	1/8/2004	Issued as U.S. Pat. No. 6,982,298 on 1/3/2006; 3rd maintenance fee due 7/3/2017	Broad macromolecular network generally; T-HA hydrogels	Licensed

Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	United States	11/176,544	7/7/2005	Issued as U.S. Pat. No. 7,465,766 on 12/16/2008; 3rd maintenance fee due 6/16/2020	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Richard A. Gross, Aniq B.Darr	United States	11/198,803	8/5/2005	Issued as U.S. Pat. No. 7,368,502 on 5/6/2008; 3rd maintenance fee due 11/06/2019	Methods of making macromolecular networks and hydrogels (Divisional of US1)	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	United States	12/283,661	9/15/2008	Issued as U.S. Pat. No. 8,207,262 on 6/26/2012; 2nd maintenance fee due 12/26/2019	Broader synthetic macromolecular network/ hydrogel claims;	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Aniq B. Darr, Richard A. Gross	United States	12/320,609	1/29/2009	Issued as U.S. Pat. No. 8,138,265 on 3/20/2012; 2nd maintenance fee due 9/20/2019	Method of making hydrogel *in situ*	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, Keiji Kamohara	United States	12/320,613	1/29/2009	Issued as U.S. Pat. No. 8,021,350 on 9/20/2011; 2nd maintenance fee due 3/20/2019	Method of treating regurgitation of cardiac valves	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Peter A. Zahos, Anthony Calabro, Aniq B. Darr, Richard A. Gross	United States	12/380,469	2/27/2009	Issued as U.S. Pat. No. 8,137,688 maintenance fee due on 9/20/2019 3/20/2012; 2nd	Synthetic nucleus pulposus	Licensed
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Richard A. Gross, Aniq B.Darr	WIPO	PCT/US2004/000478	1/9/2004	National Phase		Licensed via EP only (other jurisdictions dropped)

Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Anthony Calabro, Lee Akst, Daniel S. Alam, James Chan, Aniq B. Darr, Kiyotaka Fukamachi, Richard A. Gross, David Haynes, Keiji Kamohara, Daniel P. Knott, Hilel Lewis, Alex Melamud, Anthony Miniaci, Marshall Strome	WIPO	PCT/US2005/024391	7/8/2005	National Phase		Licensed via EP only (other jurisdictions dropped)
Hydroxyphenyl Cross-Linked Macromolecular Network and Applications Thereof	Lee Michael Akst, Daniel S. Alam, Robert Tracy Ballock, Mary P. Bronner, Michael C. Byrd, Anthony Calabro, James Chan, Aniq B. Darr, Brian L. Davis, Linda M. Graham, Richard A. Gross, Philip Daniel Knott, Peter J. Koltai, Hilel Lewis, Alex Melamud, Anthony Miniaci, George F. Muschler, Shuvo Roy, Marshall Strome	United States	60/586,585	7/9/2004	Expired	Synthetic, implantable tissue matrix; Specific synthetic tissues made of that material	Licensed through US and EP pats/apps claiming priority
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	Europe	09710120.8	2/13/2009	Issued as Pat No. 2249891; Annuity due 02/13/2017	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	Germany	09710120.8	2/13/2009	Issued as Pat No. 2249891; Annuity due 02/13/2017	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	Spain	09710120.8	2/13/2009	Issued as Pat No. 2249891; Annuity due 02/13/2017	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	France	09710120.8	2/13/2009	Issued as Pat No. 2249891; Annuity due 02/13/2017	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	United Kingdom	09710120.8	2/13/2009	Issued as Pat No. 2249891; Annuity due 02/03/2017	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	Italy	09710120.8	2/13/2009	Issued as Pat No. 2249891; Annuity due 02/13/2017	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed

Macromolecular Enhancement of Fascia Lata ECM and Methods of Use	Kathleen Derwin, Joseph Iannotti, LiKang Chin, Anthony Calabro	United States	61/065,527	2/13/2008	Expired		Licensed through issued US patent claiming priority
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	United States	12/378,296	2/13/2009	Issued as U.S. Pat. No. 8,080,260 on 12/20/2011; 2nd maintenance fee due 6/20/2019	Enhancement of ECM using Calabro material (fascia lata); Patch for tissue (e.g. tendon) repair	Licensed
Molecular Enhancement of Extracellular Matrix and Methods of Use	Kathleen Anne Derwin, Joseph Patrick Iannotti, LiKang Chin, Anthony Calabro	WIPO	PCT/US2009/034071	2/13/2009	National Phase		Licensed via EP only (other jurisdictions dropped)
Hydrogel Material for Nucleus Pulposis Replacement	Peter A. Zahos, Anthony Calabro, Aniq B. Darr	United States	61/391,909	2/27/2008	Expired	Synthetic nucleus pulposus	Licensed through US patent claiming priority
Novel Methods and Compositions to Treat Stress Urinary Incontinence	Anthony Calabro, Aniq B. Darr, Firouz Daneshgari	United States	61/049,275	4/30/2008	Expired		Licensed through issued US patent
Compositions and Methods to Treat Urinary Incontinence	Anthony Calabro, Aniq B. Darr, Firouz Daneshgari	United States	12/378,256	4/30/2009	Issued as U.S. Pat. No. 8,410,180 on 4/2/2013; 1st maintenance fee due 10/2/2016	Methods of treating SUI using hydroxyphenyl-substituted collagen network	Licensed

InSitu has also begun filing its own patent applications. The Company's focus applies specifically to drug delivery, and expands on applications and introduces concepts for tissue engineering, drug elution, different types of depots (drug any type of material that can hold an excess of drug material.

Other areas of IP focus on tuning the hydrogel to target a desired elution rate of a delivered drug or bioactive molecule. The IP describes the types of depots, or drug reservoirs, which could work with the formulation, the binding matrix that holds the depots in place during the elution process, and ways to tune the reservoirs (and matrix) to work with multiple types of drug molecules and bioactive molecules of various size and molecular weight. Finally, the Company's IP strategy contemplates all of the different formulations and configurations that can be delivered through a variety of placement devices.

Clinical Data and Process

GOOD LABORATORY PRACTICES (GLP) STUDY SUMMARY

Statistical analysis was performed by Technomics Research, LLC (Long Lake, MN, USA). The total force generated was analyzed using an unpaired *t*-test and calculated using the average force from each rat at each time point from 2 to 72 hours for 0-72 hours and from 2 to 120 hours for 0-120 hours. The difference between the right paw and left paw was evaluated using a repeated-measures analysis of variance. The area under the curve analysis was performed using the left paw average force value data and the difference was tested by an unpaired *t*-test.

Ninety rats with 30 in each group were included in the GLP portion of the study testing both mechanical allodynia and pathology. Additionally, six rats were included in the final non-GLP pharmacokinetic analysis. We first analyzed the total force generated from 2 to 72 hours after injection in the left (injured) paw. We found that the sustained release hydrogel with bupivacaine group had significantly higher force generated than the control (P=0.0004) and the liposome bupivacaine (P=0.0002) groups. We then evaluated the total force generated from 2 to 120 hours after injection. The sustained release hydrogel with bupivacaine group had significantly higher force generated when compared to the control group (P=0.0024) and the liposome bupivacaine group (P=0.0005), as shown in Tables 2 and 3. Finally, we compared the right (uninjured) to left (injured) paw values for each group and found that the right paw generated significantly higher force than the left at all time points for all three groups.

This analgesic effect of sustained release hydrogel with bupivacaine on the injured paw was supported by the data regarding the right paw. There was no significant difference between the right paw data when comparing sustained release hydrogel with bupivacaine to control and sustained release hydrogel with bupivacaine to liposome bupivacaine. This suggests that all rats performed equally well with regards to force assessment via the eVF testing in their uninjured paw and, thus, further validates testing on the injured paw. Furthermore, as there were significant differences in force generation at all time points between the left and right paws for each group, we can conclude that again force assessment via the eVF was accurate as the injured paw performed significantly worse in force assessment when compared to the uninjured paw.

Previous studies have illustrated the neurotoxic effects of local anesthetics. The neuronal injury can be characterized as either perineural inflammation or decreased number of myelinated fibers. The exact mechanism of neuronal injury is unknown; however, research suggests different mechanisms depending on the type of local anesthetic used. Furthermore, they showed that as the concentration of bupivacaine increased, there was increased neurotoxicity. Consistent with these results, the sustained release hydrogel with bupivacaine group did show some nerve damage histologically, but this damage was minimal to mild at 5 days and minimal at the 42-day time point. This likely would resolve completely over time. The liposome bupivacaine (positive control) group did not show any measurable neurotoxicity, which was similar to previous pathologic findings obtained when injected perineurally in a porcine model. As described earlier, the concentration of sustained release hydrogel with bupivacaine was higher than that of liposome bupivacaine, which may account for the differences in neuronal damage on histopathology.

Finally, the pharmacokinetic pilot study results suggest that bupivacaine remained longer in the blood of rats that received a sciatic nerve injection of sustained release hydrogel with bupivacaine than after injection of bupivacaine hydrochloride and liposome bupivacaine, indicating prolonged release. In rats weighing between 350 and 450 g, the concentrations of bupivacaine injected were between 23 and 30 mg/kg for sustained release hydrogel with bupivacaine and 3 and 3.7 mg/kg for liposome bupivacaine. Thus, the differences could be related to the differences in the concentration of bupivacaine injected. However, even at a lower concentration, liposome bupivacaine failed to produce measurable blood levels beyond 24 hours, whereas the sustained release hydrogel with bupivacaine produced measurable serum bupivacaine levels at 72 hours in one rat and 96 hours in another. Serum bupivacaine cmax levels of the sustained release hydrogel with bupivacaine are similar to previous studies involving larger dosages of liposome bupivacaine in animals.

DESCRIPTION OF PROPERTY

The Company owns no real property. The Company leases approximately 2,000 square feet of office and lab space as discussed in our section entitled "Use of Proceeds."

SELECTED FINANCIAL DATA

The following summary financial data should be read in conjunction with Management's Discussion and Analysis and the Financial Statements and Class A Common Stock thereto, included elsewhere in this Offering. The statement of operations and balance sheet data from inception through the year ended December 31, 2017 and December 31, 2018 are derived from our audited financial statements.

	As of December 31, 2017 (audited)	December 31, 2018 (audited)
TOTAL ASSETS	**$ 204,694**	**$ 1,747,300**
LIABILITIES AND SHAREHOLDERS' DEFICIT		
LIABILITIES		
Current Liabilities	126,684	96,937
Notes Payable	409,891	0
TOTAL LIABILITIES	**536,575**	**96,937**
TOTAL SHAREHOLDERS' DEFICIT	**(331,881)**	**(1,415,349)**
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	**204,694**	**1,747,300**

	Year Ended December 31, 2017 (audited)	Year Ended December 31, 2018 (audited)
Revenues	$ 0	$ 0
Expenses	275,705	917,77
Interest Income (Expense)	41,457	(1,441)
Net Loss	(317,252)	(919,218)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

You should read the following discussion and analysis of our financial condition and results of our operations together with our financial statements and related notes appearing at the end of this Offering Circular. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the section entitled "Risk Factors" and elsewhere in this Offering Circular.

BUSINESS

InSitu Biologics, Inc. (the "Company") was formed as InSitu Biologics, LLC as a Minnesota limited liability company on June 4, 2014 and was converted as a Delaware Corporation for the general purpose of engaging in any lawful activity for which corporations may be organized under the law of the State of Delaware. The Company is in the pre-clinical phase of product testing, and has not applied to the FDA for any exploration of a new drug compound.

There are three classes of stock in the Company:

1. Class B Common Stock
2. Class A Common Stock and
3. Preferred Stock

The total number of shares of all classes of stock the Company is authorized to issue is 110,000,000 shares, 10,000,000 of which are authorized as Preferred Stock; 10,000,000 of which are authorized as Class B Common Stock; and 10,000,000 of which are authorized as Class A Common Stock. The Shares being sold in this Offering are all Class A Common Stock.

As of December 31, 2018 , there were 3,153,203 shares of Class A Common Stock outstanding (pre-split.) There were 1,500,000 shares of Class B Common Stock outstanding (pre-split.) As of October 18, 2019, there were 2,867,114 shares of Class A Common Stock outstanding (post-splits) and 3,000,000 shares of Class B Common Stock outstanding (post-split.)

Description of Rights of Classes of Stock

All Shares of Class A Common Stock shall be identical and have one vote per share. The Shares to be issued pursuant to this Offering will be Class A Common Stock. All holders of shares of Class B Common Stock (which are not being sold in this Offering) shall be identical and shall at every meeting of the stockholders be entitled to two votes for each share of the capital stock held by such stockholder. All of the other terms (except for voting) of the Class A Common Stock shall be identical to the Class B Common Stock, except for the right of first refusal that attaches to the Class A Common Stock, as explained in this Offering Circular and in the Company's Bylaws.

The Preferred Stock was convertible to the Class A Common Stock on a 1 to 1.1 basis meaning for every Preferred Share owned by a Shareholder. The shares converted into 1.1 shares of Class A Common Stock after the Regulation A+ offering was qualified by the Securities Exchange Commission.

Results of Operations

The six-months ended June 30, 2019

Revenue. Total revenue for the six-months ended June 30, 2019 was $0. June 4, 2014 (date of inception) to June 30, 2019, the Company was in the start-up phase.

Operating Expenses. Operating expenses for the six-months ended June 30, 2019 were $917,777. Operating expenses for the period were comprised of research and development expenses and general administrative expenses.

Net Loss. The Company incurred a net loss of ($919,218) for the six-months ended June 30, 2019 which included $1,441 in interest expense.

The year ended December 31, 2018

Revenue. Total revenue for the year ended December 31, 2018 was $0. June 4, 2014 (date of inception) to December 31, 2018, the Company was in the start-up phase.

Operating Expenses. Operating expenses for the year ended December 31, 2018 were $917,777. Operating expenses for the period were comprised of research and development expenses and general administrative expenses.

Net Loss. The Company incurred a net loss of ($919,218) for the year ended December 31, 2018 which included $1,441 in interest expense.

Liquidity and Capital Resources

The Company had net cash of $1,027,616 at June 30, 2019.

During the six-months ended June 30, 2019, we used $917,777 of cash to cover the operating expenses. For the period ended December 31, 2017, cash was used for operating expenses of $1,001,536.

For the six-months ended June 30, 2019, $2,055 was recognized as interest income.
The Company had net cash of $1,725,585 at December 31, 2018 compared to net cash of $147,852 as of December 31, 2017. Cash as of December 31, 2016 was $209,158. The increase in 2 018 was due to our fundraising efforts under Regulation A + and the sale of shares of our Class A common stock.

During the year ended December 31, 2018, we used $917,777 of cash to cover the operating expenses. For the year ended December 31, 2017, cash was used for operating expenses of $301,054. For the year ended December 31, 2016, cash was used for operating expenses of $300,554.

For the year ended December 31, 2018, $1,441 of Company cash was used for interest expense. For theyear ended December 31, 2017 $41,547 of Company cash was used for interest expense were met by the founders. For the year ended December 31, 2016, the interest expense was $30,000. The decrease was due to the conversion of notes into stock and the payoff of debt.

At August 7, 2018, the Company had sold 262,360 shares at $5.75 per share since the Regulation A Offering was qualified. Due to the popularity of the shares and in an effort to maximize shareholder value, the Company increased the share price to $6.85 per share. The Company sold 275,661 shares at $5.75 per share, 43,126 shares at $6.85 per share, and 31,588 shares at $6.90 since our Offering was qualified. Due to the popularity of the shares and in an effort to maximize shareholder value, we are increasing our share price to $8.00 per share. Effective February 25, 2019, the Board of Directors consented to a 2 to 1 stock split resulting in 3,155,757 Class A shares outstanding. During the period January 1, 2019 through July 16, 2019, the Company raised and additional $878,760 of equity through sales of Common Stock.

The Company believes that funding at any level could result in significant progress being made toward gaining the Phase 1 Clinical Study. The Company has not yet applied for an Investigational New Drug ("IND"). The Company has completed the capital acquisition of its laboratory equipment and further laboratory expenses are directly related to compounding products. The Company has the ability to slow down or accelerate product development, pre-clinical studies, and clinical studies based on available funds. Nearly all expenses are variable, and employees are willing to delay compensation from time to time if need be.

Related Party Transactions

In June 2017, the Company entered into a line of credit ("LOC") for continued financing of the Company's operating expenses. This senior non-subordinated LOC provides for up to $130,000 of funding to be repaid at the non-usurious interest rate of 6%. As of December 31, 2017, the Company had accessed approximately $109,891 of the available funds.

In exchange for waiving all of the rights granted to 524 Investments, LLC in connection with their First Round Investment of $1,000,000 resulting in 99.95% of all equity purchased, with the exception of a board seat appointment, 524 Investments shall maintain shares which allow them 2 votes for every Class B Share.

In January 2018 the related party note and all other Noteholders agreed to convert their Notes to the shares under the terms of the current Preferred Stock Offering. The notes and accrued interest were converted into 95,131 preferred shares at a conversion rate of five to one. The Preference is 10% more shares upon conversion to Common A shares when the Company conducts its anticipated Regulation A Plus Offering. In receiving that discount as part of the debt conversion in January 2018, Noteholders also agreed to accept a 6% interest rate instead of the 10% interest rate.

The Company sold an additional 48,801 Preferred Shares for a total of $220,487 net of offering costs.

Trend Information

Because we are still in the startup phase and have only recently launched the Company, we are unable to identify any recent trends in site visitations, revenue or expenses since the latest financial year. Thus, we are unable to identify any known trends, uncertainties, demands, commitments or events involving our business that are reasonably likely to have a material effect on our revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause the reported financial information in this Offering to not be indicative of future operating results or financial condition.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Critical Accounting Policies

We have identified the policies outlined in this Offering Circular and attachments as critical to our business operations and an understanding of our results of operations. Those policies outlined are not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management's judgment in their application. The impact and any associated risks related to these policies on our business operations is discussed throughout Management's Discussion and Analysis of Financial Condition and Results of Operation where such policies affect our reported and expected financial results. Note that our preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of our consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. There can be no assurance that actual results will not differ from those estimates.

Revenue Recognition

The Company had no revenue during 2017 or 2018. The Company had no product returns during 2017 or 2018.

Additional Company Matters

The Company has not filed for bankruptcy protection nor has it ever been involved in receivership or similar proceedings. The Company is not presently involved in any legal proceedings material to the business or financial condition of the Company. The Company does not anticipate any material reclassification, merger, consolidation, or purchase or sale of a significant proportion of assets (not in the ordinary course of business) during the next 12 months.

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

The directors, executive officers and significant employees of the Company as of the date of this filing are as follows:

Name	Position	Age	Term of Office	PT Hours (1)	FT Hours (2)
Executive Officers					
Kevin Bassett	CEO, President,	51		NA	40
James Knapp	Chairman Treasurer	42		10	NA
William Taylor	CSO, Secretary	47		NA	40
Directors					
Robert Wilson	Director	66		NA	40
James Knapp	Director	42		10	NA
William Taylor	Director	47		NA	40

(1) Approximate Hours Worked Per Week For Part Time Employee
(2) Approximate Hours Worked Per Week For Full Time Employee

Directors, Executive Officers and Significant Employees

As of the date of this filing, INSITU BIOLOGICS has two full-time employees. It has also established a business board of directors. In addition, INSITU BIOLOGICS has engaged with other key individuals possessing a range of expertise including mechanical engineering, process engineering, software engineering, computational modeling and other areas. These additional key individuals could start employment at INSITU BIOLOGICS at such time as the company has sufficient capital or financing to fund the expanded launch of its business activities and research and development.

The number of business and direct research personnel hired by INSITU BIOLOGICS will scale based upon funds raised in the equity crowdfunding offering and as operating needs warrant. Certain skilled executive positions, such as a person to manage U.S. FDA requirements, could be filled in a timely fashion as the business progresses, but most likely the use of consultants and experts in the field could prove to be a more productive and cost effective means of handling requirements.

INSITU BIOLOGICS board members serve unless and until a successor is elected and qualified. Board members will not receive compensation for attendance in board meetings, but may be reimbursed for reasonable expenses incurred during the course of their performance. Personnel currently serving as officers and board members of INSITU BIOLOGICS include:

Kevin Bassett, M.B.A. – President and CEO

Kevin Bassett joined Insitu Biologics in September 2019 as President and CEO. Prior to joining Insitu, Mr. Bassett was General Manager of HLT Medical, a clinical-stage company developing a next-generation heart valve in the field of Transcatheter Aortic Valve Replacement (TAVR). Kevin has also served in a variety of senior executive roles in early-stage medical technology companies over the past twenty years.

Mr. Bassett is a certified public accountant (inactive license). He holds an M.B.A. from the Carlson School of Management at the University of Minnesota and a B.A. in Accounting and English from St. John's University. Kevin also held a commission as an officer in the United States Army Reserves from 1991 – 2001.

James Knapp, Chairman, Board of Directors

James Knapp has served on the Board of InSitu since May of 2015. James, CRPC, CFP, APMA is the President of Heritage Wealth Architects, a financial advisory firm that James founded in 2012. James is responsible for leading all aspects of the firm. Earlier in his career, as a CFP, James led a franchise for one of the largest financial planning firms in the country. James specializes in advising executives, small business owners, and high net-worth individuals concerned with tax-planning, compensation, buying, growing or selling their businesses. James started HWA as a fee for service firm with a vision to provide clients with a personalized, flexible and thorough array of options to create and conserve wealth. At the center of his client-focused firm is the commitment to honor his fiduciary responsibilities, and really listen to each individual's goals and dreams. James is a Business Management graduate of Luther College, and lives in St. Paul, where he enjoys spending time with his family, traveling, hunting, fishing, climbing mountains and playing golf.

Robert Wilson, MD – Member of the Board of Directors

Dr. Wilson has dedicated his professional life to developing new methods for diagnosing and treating heart disease, and to training new physicians. He presently directs the University of Minnesota interventional-cardiology fellowship program and University of Minnesota Physicians clinical cardiovascular services.

A graduate of the University of Iowa College of Medicine, Dr. Wilson completed his residency at the University of Texas Health Science Center at San Antonio and his cardiology fellowship at the University of Iowa. He joined the University of Minnesota faculty in 1986, when he and Dr. Carl White established a training program that has graduated over 50 interventional cardiologists. From 1988-2004, Dr. Wilson served as the director of the University of Minnesota Medical Center-Fairview's cardiac catheterization laboratory.

Dr. Wilson's investigative career initially focused on coronary physiology in humans. He developed the first catheter for the selective measure of coronary bloodflow in humans, and described the effects of atherosclerosis and transplantation on coronary bloodflow. He also first identified reinnervation of the transplanted human heart and its effects on cardiac function. Later, Dr. Wilson developed semi-computerized injection systems for coronary angiography that now used annually for millions of patients worldwide.

Dr. Wilson's present research focus is the development of a prosthetic heart valve that can be inserted through a small catheter, eliminating the need for open-heart valve surgery. This device is now in human clinical trials.

Dr. Wilson holds numerous patents for cardiovascular treatment devices. The National Institute of Health, the American Heart Association, and private individuals have supported his work.

William J. Taylor, Chief Scientist

Bill Taylor has served on the Board of InSitu since its inception in 2014. Bill became an employee at InSitu Biologics on January 1, 2018. Bill is a successful medical device development program manager and scientist. From May 2011 through October 2017, Bill lead multiple projects for ACIST Medical Systems including CVi - A2000V, CVi - CPT2000, and RXi rapid exchange FFR system and Navvus catheter; an ultrathin microcatheter pressure sensor. In 2007, Bill was recruited to lead a biohydrogel technology development program in cooperation with the Cleveland Clinic Foundation and was able to complete biocompatibility testing, fundamental physical and chemical property design package, initial application identification and start feasibility analysis. Bill was the lead project manager in the construction, qualification and validation of PDL Biopharma's (formerly Protein Design Labs, Inc.) state-of-the-art, $200 million production facility in Brooklyn Park, MN. Throughout his career he has been the program manager in medical device and biopharmaceutical product development including Retavase (Roche), Osteoarthritis injectable, and several consumable kits. Prior to 2004, Bill was a principal scientist, inventor and program manager at Gradient Technology. Bill has authored industry papers in chemical remediation and demilitarization utilizing biological systems.

Bill has his Bachelor of Science from the University of Minnesota with a double major in Chemical Engineering and Biology.

COMPENSATION OF DIRECTORS AND EXECUTIVE OFFICERS

From inception to the date of this Offering, the Company has paid no compensation to its officers or directors. The Company may hire additional officers in the future and pay them directly, and may choose to compensate its directors in the future.

Name	Capacity in which compensation was received	Cash Compensation ($)	Other Compensation ($)	Total Compensation ($)
Executive Officers				
Kevin Bassett	CEO and President	$ 220,000	$ 0	$ 220,000
James Segermark	Former CEO, President and Secretary	$ 144,000	$ 0	$ 144,000
James Knapp	CFO and Treasurer	$ 36,000	$ 0	$ 36,000
William Taylor	Chief Scientific Officer	$ 144,000	$ 0	$ 144,000
Directors				
Robert Wilson	Director	$ 0	$ 0	$ 0
James Knapp	Director	$ 0	$ 0	$ 0
William Taylor	Director	$ 0	$ 0	$ 0

Advisory Agreements

The Company has agreed to pay FundAthena, Inc., doing business as Manhattan Street Capital (“Manhattan Street Capital”) for its services in hosting the offering of the shares on its online platform. This compensation consists of: (i) $25 per investor in cash paid when such investor deposits funds into escrow; minimum $5,000 per month while the offering is live to investors (ii) a warrant to purchase that number of shares of Common Stock determined by multiplying $25 by the total number of investors in this offering and dividing by the price at which our common stock is sold in this offering, The warrants will have an exercise price equal to the price at which our common stock is sold in this offering. Manhattan Street Capital does not directly solicit or communicate with investors with respect to offerings posted on its site, although it does advertise the existence of its platform, which may include identifying a broad selection of issuers listed on the platform. Warrants will be delivered to Manhattan Street Capital promptly upon the close of the offering. If the offering does not complete successfully for any reason, the warrants earned will be promptly delivered to Manhattan Street Capital. Payments of cash and warrants to Manhattan Street Capital are not contingent upon the success of the offering.

Employment Agreements

The Company has not entered into any employment agreements with its executive officers or other employees to date. It may enter into employment agreements with them in the future.

Stock Incentive Plan

In the future, the Company may establish a management stock incentive plan pursuant to which stock options and awards may be authorized and granted to our directors, executive officers, employees and key employees or consultants. Details of such a plan, should one be established, have not been decided upon as of the date of this Offering. Stock options or a significant equity ownership position in the Company may be utilized by us in the future to attract one or more new key senior executives to manage and facilitate our growth.

Cash Incentive Plan (CIP)

The Board of Directors has proposed, and Shareholders have approved, a cash payment plan for Segermark, Taylor and Knapp, that aligns Shareholder goals in growing value and monetizing their investment with a cash payment to each of the named participants in the CIP. The CIP is being developed, however, the basic outline of the CIP is as follows:

1. For the initial $50,000,000 realized by the Company in total remuneration from the sale or license of AnestaGel or any of the Company's related technology, One Percent (1%) of those monies shall go in to a pool to be paid to the plan participants.

2. Each additional $50,000,000 realized by the Company in total remuneration from the sale or license per above, shall compound one more percent to each payment and each payment shall be reconciled to the first dollar of the Transaction. The CIP shall be capped at 12% of total remuneration. If this Tier of 12% were to be reached, it would mean that the Transaction was minimally worth $600,000,000 to the Company.

3. For as long as payments are made for the Transaction to the Company and its successors and/or assigns, the CIP shall be paid to its Participants.

Board of Directors

Our board of directors currently consists of three directors:

None of our directors are "independent" as defined in Rule 4200 of FINRA's listing standards. We may appoint an independent director(s) to our board of directors in the future, particularly to serve on appropriate committees should they be established.

Committees of the Board of Directors

We may establish an audit committee, compensation committee, a nominating and governance committee and other committees to our Board of Directors in the future, but have not done so as of the date of this Offering Circular. Until such committees are established, matters that would otherwise be addressed by such committees will be acted upon by the entire Board of Directors.

Director Compensation

We currently do not pay our directors any compensation for their services as board members, with the exception of reimbursing and board related expenses. In the future, we may compensate directors, particularly those who are not also employees and who act as independent board members, on either a per meeting or fixed compensation basis.

Limitation of Liability and Indemnification of Officers and Directors

Our Bylaws limit the liability of directors and officers of the Company. The Bylaws state that the Company shall indemnify, in accordance with and to the full extent now or hereafter permitted by law, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (including, without limitation, an action by or in the right of the corporation), by reason of his or her acting as a director or officer of the corporation (or a director or officer serving at the request of the corporation in any other capacity for or on behalf of the corporation) against any expenses (including attorneys' fees, judgments, fines, ERISA or other excise taxes, penalties and amounts paid in settlement) actually and reasonably incurred by such director or officer in respect thereof; provided, however, that, the corporation shall not be obligated to indemnify any such director or officer with respect to proceedings, claims or actions initiated or brought voluntarily by such director and not by way of defense. Expenses that may be subject to indemnification hereunder shall be paid in advance of the final disposition of the action, suit or proceeding to the full extent permitted by Delaware law subject to the corporation's receipt of any undertaking required thereby. The provisions of this article of the Company's Bylaws shall be deemed to constitute a contract between the Company and each director or officer who serves in such capacity at any time while this article and the relevant provisions of Delaware law are in effect, and each such director or officer shall be deemed to be serving as such in reliance on the provisions of this article of the Company's Bylaws, and any repeal of any such provisions or of such article of the Company's Bylaws shall not affect any rights or obligations then existing with respect to any state of facts then or theretofore existing or any action, suit or proceeding theretofore or thereafter brought or threatened based in whole or in part upon any such state of facts. If a claim under this article of the Company's Bylaws is not paid in full within thirty (30) days after a written claim has been received by the corporation, the claimant may at any time thereafter bring suit against the corporation to recover the unpaid amount of the claim and, if successful in whole or in part, the claimant also shall be entitled to be paid the expense of prosecuting such claim. It shall be a defense to any such action (other than an action brought to enforce a claim for expenses incurred in defending any proceeding in advance of its final disposition where the required undertaking, if any, has been provided to the corporation) that the claimant has not met the standards of conduct that make it permissible under Delaware law for the corporation to indemnify the claimant for the amount claimed, but the burden of proving such defense shall be on the corporation. Neither the failure of the corporation to have made a determination prior to the commencement of such action that indemnification of the claimant is proper under the circumstances because the claimant has met the applicable standard of conduct set forth in the Delaware law, nor an actual determination by the corporation that the claimant has not met such standard of conduct shall be a defense to the action or create a presumption that the claimant has not met the applicable standard of conduct. The rights of indemnification and advancement provided by this article of the Company's Bylaws are not exclusive of any other right to indemnification or advancement provided by law, agreement or otherwise, and shall apply to actions, suits or proceedings commenced after the date hereof, whether or not arising from acts or omissions occurring before or after the adoption hereof, and shall continue as to a person who has ceased to be a director or officer of the corporation and shall inure to the benefit of the heirs, executors and administrators of such a person.

There is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

For additional information on indemnification and limitations on liability of our directors and officers, please review the Company's Bylaws, which are attached to this Offering Circular.

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS

Beneficial ownership and percentage ownership are determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to shares of the Company's stock. This information does not necessarily indicate beneficial ownership for any other purpose.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each shareholder named in the following table possesses sole voting and investment power over their shares of the Company's stock.

The following table sets forth information regarding beneficial ownership of all classes of our stock by any of our directors or executive officers as of the date of the Regulation A offering:

Column1	Class A Common Prior To Offering	Percentage	Class A Common After Offering	Percentage	Class B Common Before Offering	Percentage	Class B Common After Offering	Percentage
Joseph Glab	500,000	20%	231,400	7%	0	0%	0	0%
James Segermark	465,000	19%	276,779	9%	0	0%	0	0%
Stefano Sinicropi	500,000	20%	250,000	8%	0	0%	0	0%
Daniel Sipple	500,000	20%	285,894	9%	0	0%	0	0%
William Taylor	500,000	20%	250,073	8%	0	0%	0	0%
524 Investments, LLC (1)	0	0%	49,780	2%	3,000,000	100%	3,000,000	100%
Conrad Tanasychuk	0	0%	79,658	3%	0	0%	0	0%
New Shares Under Regulation A Offering	NA	NA	1,739,132	55%	NA	0%	NA	0%
Total Shares	2,465,000	100%	3,162,716	100%	3,000,000	100%	3,000,000	100%

(1) 524 Investments, LLC is managed by James Knapp.

CAPITALIZATION TABLE

The following table sets forth information regarding ownership by class of stock of our Preferred Stock, Class B Common Stock, and Class A Common Stock by all shareholders as of the date of this Regulation A offering.

Name	Class A Common Shares	Class B Common Shares	Preferred Shares	TOTAL	Percentage
Joseph Glab	230,000	0	0	230,000	3.94%
James Segermark	185,603	0	0	185,603	4.72%
Stefano Sinicropi	250,000	0	0	250,000	4.26%
Daniel Sipple	247,500	0	0	247,500	4.87%
William Taylor	250,073	0	0	250,073	4.26%
James Knapp	23,470	0	0	23,470	0.40%
Jake Hutchins	30,000	0	0	30,000	0.51%
Private Offering Investors and Convertible Notes (1)	266,852	0	0	266,852	4.55%
524 Investments, LLC (2)	49,780	3,000,000	0	3,049,780	51.98%
Conrad Tanasychuk	79,658	0	0	79,658	1.36%
New Shares under Regulation A Offering	1,123,208	0	0	1,123,208	19.14%
Total Shares	2,867,114	3,000,000	0	5,867,114	
Cumulative Total				5,867,114	100%

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(1) From July through October 2014, we entered into a Convertible Loan Agreement (the “Loan Agreement”) with five individuals. The principal loan amounts total $300,000 and accrued interest at a rate of 10% annually. In January 2018 the related party note and all other Noteholders agreed to convert their Notes to the shares under the terms of the current Preferred Stock Offering. The notes and accrued interest were converted into 95,131 (pre-split) preferred shares at a conversion rate of five to one. The Preference is 10% more shares upon conversion to Common A shares when the Company conducts its anticipated Regulation A Plus Offering. In receiving that discount as part of the debt conversion in January 2018, Noteholders also agreed to accept a 6% interest rate instead of the 10% interest rate. These Preferred Shares have since been converted to Class A Common Shares at a rate of 1 to 1.1.

(2) James Knapp beneficially owns the shares issued to 524 Investments, LLC

INTEREST OF MANAGEMENT AND OTHERS IN CERTAIN RELATED-PARTY TRANSACTIONS AND AGREEMENTS

From July through October 2014, we entered into a Convertible Loan Agreement (the “Loan Agreement”) with five individuals. The principal loan amounts total $300,000 and accrued interest at a rate of 10% annually. In January 2018 the related party note and all other Noteholders agreed to convert their Notes to the shares under the terms of the current Preferred Stock Offering. The notes and accrued interest were converted into 95,131 (pre-split) preferred shares at a conversion rate of five to one. The Preference is 10% more shares upon conversion to Common A shares when the Company conducts its anticipated Regulation A Plus Offering. In receiving that discount as part of the debt conversion in January 2018, Noteholders also agreed to accept a 6% interest rate instead of the 10% interest rate.

Further, an initial investor 524 Investments, LLC was issued units originally in InSitu Biologics, LLC. In the conversion of the LLC to the current Delaware corporation, the Company has elected to issue Class B Common Shares to the 524 Investments, LLC.

Class B Common Shares are entitled to two votes for every share held by 524 Investments, LLC. Currently, 524 Investments, LLC holds 3,000,000 (post-split) shares of Class B Common Stock. Further, 524 Investments, LLC, as the sole holder of Class B Common Stock, is entitled to appoint one director to the Board of Directors for an initial term. Thereafter, the board member must stand for reelection. The initial term shall be for three (3) years.

On October 18, 2019, five founders of the Company agreed to a 4 to 1 reverse stock split of their own shares obtained for founding the Company. This resulted in outstanding Class A shares of 2,867,114.

SECURITIES BEING OFFERED

The Company is offering Shares of its Class A Common Stock. Except as otherwise required by law, the Company's Bylaws or its Certificate of Incorporation, each Class A Common Stock shareholder shall not be entitled to vote. The Shares of Class A Common Stock, when issued, will be fully paid and non-assessable. Since the holders of Class A Common Stock issued pursuant to this Offering Circular do have voting rights with one vote per share. However, the Class B Shares have 2 votes per share and therefore, the Class A shareholders should not expect to be able to influence any decisions by management of the Company through voting on Company matters.

There is one other class of stock in the Company as of the date of this Offering Circular. The Company does not expect to create any additional classes of stock during the next 12 months, but the Company is not limited from creating additional classes which may have preferred dividend, voting and/or liquidation rights or other benefits not available to holders of its Class A Common Stock if it chooses to do so.

The Company does not expect to declare dividends for holders of Class A Common Stock in the foreseeable future. Dividends will be declared, if at all (and subject to the rights of holders of additional classes of securities, if any), in the discretion of the Company's Board of Directors. Dividends, if ever declared, may be paid in cash, in property, or in shares of the capital stock of the Company, subject to the provisions of law, the Company's Bylaws and the Certificate of Incorporation. Before payment of any dividend, there may be set aside out of any funds of the Company available for dividends such sums as the Board of Directors, in its absolute discretion, deems proper as a reserve for working capital, to meet contingencies, for equalizing dividends, for repairing or maintaining any property of the Company, or for such other purposes as the Board of Directors shall deem in the best interests of the Company.

There is no minimum number of Shares that needs to be sold in order for funds to be released to the Company and for this Offering to close. The Company anticipates numerous closings to take place during the Offering.

The minimum subscription that will be accepted from an investor is Two Thousand Four Hundred Sixty Dollars ($2,460.00) (the "Minimum Subscription"). A subscription for Two Thousand Four Hundred Sixty ($2,460.00) or more in the Shares may be made only by tendering to the Company the executed Subscription Agreement (electronically or in writing) delivered with the subscription price in a form acceptable to the Company, via check, wire, or ACH (or other payment methods the Company may later add). The execution and tender of the documents required, as detailed in the materials, constitutes a binding offer to purchase the number of Shares stipulated therein and an agreement to hold the offer open until the expiration date or until the offer is accepted or rejected by the Company, whichever occurs first.

The Company reserves the unqualified discretionary right to reject any subscription for Shares, in whole or in part. If the Company rejects any offer to subscribe for the Shares, it will return the subscription payment, without interest or reduction. The Company's acceptance of your subscription will be effective when an authorized representative of the Company issues you written or electronic notification that the subscription was accepted.

There is a right of first refusal attached to the Class A Common Stock in this Offering. Aside from this restriction, there are no liquidation rights, preemptive rights, conversion rights, redemption provisions, sinking fund provisions, impacts on classification of the Board of Directors where cumulative voting is permitted or required related to the Class A Common Stock, provisions discriminating against any existing or prospective holder of the Class A Common Stock as a result of such Shareholder owning a substantial amount of securities, or rights of Shareholders that may be modified otherwise than by a vote of a majority or more of the Shares outstanding, voting as a class defined in any corporate document as of the date of filing. The Class A Common Stock will not be subject to further calls or assessment by the Company. There are no restrictions on alienability of the Class A Common Stock in the corporate documents other than a right of first refusal and those disclosed in this Offering Circular. The Company intends to engage a transfer agent and registrant for the Shares. For additional information regarding the Shares, please review the Company's Bylaws, which are attached to this Offering Circular. There are no restrictions on alienability other than the right of first refusal.

The right of first refusal is defined in the Company's Bylaws as follows:

Restrictions on Transfers of Shares. Until the Common Stock of the corporation is listed on an exchange and is made available for trading, no stockholder shall sell, assign, pledge or in any manner transfer any of the shares of Common Stock of the corporation or any right or interest therein, whether voluntarily or by operation of law, or by gift or otherwise, except by a transfer which meets the requirements hereinafter set forth in this Section.

(a) If the stockholder receives from anyone a bona fide offer acceptable to the stockholder to purchase any of its shares of Common Stock, then the stockholder shall first give written notice thereof to the corporation. The notice shall name the proposed transferee and state the number of shares to be transferred, the price per share and all other terms and conditions of the offer.

(b) For ten (10) days following receipt of such notice, the corporation shall have the option to purchase all (but not less than all) the shares specified in the notice at the price and upon the terms set forth in such bona fide offer. In the event the corporation elects to purchase all the shares, it shall give written notice to the selling stockholder of its election and settlement for said shares shall be made as provided below in paragraph (c).

(c) In the event the corporation elects to acquire the shares of the selling stockholder as specified in said selling stockholder's notice, the Secretary of the corporation shall so notify the selling stockholder and settlement thereof shall be made in cash within fifteen (15) days after the Secretary of the corporation receives said selling stockholder's notice; provided that if the terms of payment set forth in said selling stockholder's notice were other than cash against delivery, the corporation shall pay for said shares on the same terms and conditions set forth in said selling stockholder's notice.

(d) In the event the corporation does not elect to acquire all of the shares specified in the selling stockholder's notice, said selling stockholder may, within a sixty-day period following the expiration of the rights granted to the corporation herein, sell elsewhere the shares specified in said selling stockholder's notice which were not acquired by the corporation, in accordance with the provisions of paragraph (c) of this Section provided that said sale shall not be on terms and conditions more favorable to the purchaser than those contained in the bona fide offer set forth in said selling stockholder's notice. All shares so sold by said selling stockholder shall continue to be subject to the provisions of this Section in the same manner as before said transfer.

(e) Anything to the contrary contained herein notwithstanding, the following transactions shall be exempt from the provisions of this Section:

(i) A stockholder's transfer of any or all shares held either during such stockholder's lifetime or on death by will or intestacy to such stockholder's immediate family. "Immediate family" as used herein shall mean spouse, lineal descendant, father, mother, brother, or sister of the stockholder making such transfer and shall include any trust established primarily for the benefit of the stockholder or his immediate family.

(ii) A stockholder's bona fide pledge or mortgage of any shares with a commercial lending institution, provided that any subsequent transfer of said shares by said
institution shall be conducted in the manner set forth in this Section.

(iii) A stockholder's transfer of any or all of such stockholder's shares to the corporation.

(iv) A corporate stockholder's transfer of any or all of its shares to an affiliate thereof or pursuant to and in accordance with the terms of any merger, consolidation, or reclassification of shares or capital reorganization of the corporate stockholder.

(v) A corporate stockholder's transfer of any or all of its shares to any or all of its stockholders.

(vi) A transfer by a stockholder which is limited or general partnership to any or all of its partners or retired partners, or to any such partner's or retired partner's estate. In any such case, the transferee, assignee or other recipient shall receive and hold such Common Stock subject to the provisions of this Section 8.14, and there shall be no further transfer of such Common Stock except in accordance with this Section.

(f) The provisions of this Section may be waived with respect to any transfer either by the corporation, upon duly authorized action of the Board of Directors, or by the stockholders, upon the express written consent of the owners of a majority of the voting power of the corporation (excluding the votes represented by those shares to be sold by the selling stockholder). This Section may be amended or repealed only upon the express vote or written consent of the owners of a majority of the voting power of each outstanding class of voting securities of the corporation or by the duly authorized action of the Board of Directors.

(g) Any sale or transfer, or purported sale or transfer, of securities of the corporation shall be null and void unless the terms, conditions, and provisions of this Section are strictly observed and followed.

(h) The foregoing right of first refusal shall automatically terminate upon the date securities of the corporation are first offered to the public pursuant to a registration statement filed with, and declared effective by, the United States Securities and Exchange Commission under the Securities Act of 1933, as amended, or upon the listing of the securities of the corporation on any stock exchange subject to the Securities Exchange Act of 1934. These provisions of this Section shall also not apply to the corporation's securities that are sold or granted to shareholders in any private placement or securities prior to the date securities of the corporation are first offered to the public pursuant to a Regulation A offering qualified by the United States Securities and Exchange Commission.

INTERESTS OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this Offering as having prepared or certified any part of this Offering or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the Shares was employed on a contingency basis, or had, or is to receive, in connection with the Offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

Trowbridge Sidoti LLP is providing legal services relating to the Form 1-A.

DISQUALIFYING EVENTS DISCLOSURE

Recent changes to Regulation A promulgated under the Securities Act prohibit an issuer from claiming an exemption from registration of its securities under such rule if the issuer, any of its predecessors, any affiliated issuer, any director, executive officer, other officer participating in the offering of the interests, general partner or managing member of the issuer, any beneficial owner of 20% or more of the voting power of the issuer's outstanding voting equity securities, any promoter connected with the issuer in any capacity as of the date hereof, any investment manager of the issuer, any person that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with such sale of the issuer's interests, any general partner or managing member of any such investment manager or solicitor, or any director, executive officer or other officer participating in the offering of any such investment manager or solicitor or general partner or managing member of such investment manager or solicitor has been subject to certain "Disqualifying Events" described in Rule 506(d)(1) of Regulation D subsequent to September 23, 2013, subject to certain limited exceptions. The Company is required to exercise reasonable care in conducting an inquiry to determine whether any such persons have been subject to such Disqualifying Events and is required to disclose any Disqualifying Events that occurred prior to September 23, 2013 to investors in the Company. The Company believes that it has exercised reasonable care in conducting an inquiry into Disqualifying Events by the foregoing persons and is aware of the no such Disqualifying Events.

It is possible that (a) Disqualifying Events may exist of which the Company is not aware and (b) the SEC, a court or other finder of fact may determine that the steps that the Company has taken to conduct its inquiry were inadequate and did not constitute reasonable care. If such a finding were made, the Company may lose its ability to rely upon exemptions under Regulation A, and, depending on the circumstances, may be required to register the Offering of the Company's Class A Common Stock with the SEC and under applicable state securities laws or to conduct a rescission offer with respect to the securities sold in the Offering.

ERISA CONSIDERATIONS

Trustees and other fiduciaries of qualified retirement plans or IRAs that are set up as part of a plan sponsored and maintained by an employer, as well as trustees and fiduciaries of Keogh Plans under which employees, in addition to self-employed individuals, are participants (together, "ERISA Plans"), are governed by the fiduciary responsibility provisions of Title 1 of the Employee Retirement Income Security Act of 1974 ("ERISA"). An investment in the Shares by an ERISA Plan must be made in accordance with the general obligation of fiduciaries under ERISA to discharge their duties (i) for the exclusive purpose of providing benefits to participants and their beneficiaries; (ii) with the same standard of care that would be exercised by a prudent man familiar with such matters acting under similar circumstances; (iii) in such a manner as to diversify the investments of the plan, unless it is clearly prudent not do so; and (iv) in accordance with the documents establishing the plan. Fiduciaries considering an investment in the Shares should accordingly consult their own legal advisors if they have any concern as to whether the investment would be inconsistent with any of these criteria.

Fiduciaries of certain ERISA Plans which provide for individual accounts (for example, those which qualify under Section 401(k) of the Code, Keogh Plans and IRAs) and which permit a beneficiary to exercise independent control over the assets in his individual account, will not be liable for any investment loss or for any breach of the prudence or diversification obligations which results from the exercise of such control by the beneficiary, nor will the beneficiary be deemed to be a fiduciary subject to the general fiduciary obligations merely by virtue of his exercise of such control. On October 13, 1992, the Department of Labor issued regulations establishing criteria for determining whether the extent of a beneficiary's independent control over the assets in his account is adequate to relieve the ERISA Plan's fiduciaries of their obligations with respect to an investment directed by the beneficiary. Under the regulations, the beneficiary must not only exercise actual, independent control in directing the particular investment transaction, but also the ERISA Plan must give the participant or beneficiary a reasonable opportunity to exercise such control, and must permit him to choose among a broad range of investment alternatives.

Trustees and other fiduciaries making the investment decision for any qualified retirement plan, IRA or Keogh Plan (or beneficiaries exercising control over their individual accounts) should also consider the application of the prohibited transactions provisions of ERISA and the Code in making their investment decision. Sales and certain other transactions between a qualified retirement plan, IRA or Keogh Plan and certain persons related to it (*e.g.,* a plan sponsor, fiduciary, or service provider) are prohibited transactions. The particular facts concerning the sponsorship, operations and other investments of a qualified retirement plan, IRA or Keogh Plan may cause a wide range of persons to be treated as parties in interest or disqualified persons with respect to it. Any fiduciary, participant or beneficiary considering an investment in Shares by a qualified retirement plan IRA or Keogh Plan should examine the individual circumstances of that plan to determine that the investment will not be a prohibited transaction. Fiduciaries, participants or beneficiaries considering an investment in the Shares should consult their own legal advisors if they have any concern as to whether the investment would be a prohibited transaction.

Regulations issued on November 13, 1986, by the Department of Labor (the "Final Plan Assets Regulations") provide that when an ERISA Plan or any other plan covered by Code Section 4975 (*e.g.*, an IRA or a Keogh Plan which covers only self-employed persons) makes an investment in an equity interest of an entity that is neither a "publicly offered security" nor a security issued by an investment company registered under the Investment Company Act of 1940, the underlying assets of the entity in which the investment is made could be treated as assets of the investing plan (referred to in ERISA as "plan assets"). Programs which are deemed to be operating companies or which do not issue more than 25% of their equity interests to ERISA Plans are exempt from being designated as holding "plan assets." Management anticipates that we would clearly be characterized as an "operating company" for the purposes of the regulations, and that it would therefore not be deemed to be holding "plan assets."

Classification of our assets of as "plan assets" could adversely affect both the plan fiduciary and management. The term "fiduciary" is defined generally to include any person who exercises any authority or control over the management or disposition of plan assets. Thus, classification of our assets as plan assets could make the management a "fiduciary" of an investing plan. If our assets are deemed to be plan assets of investor plans, transactions which may occur in the course of its operations may constitute violations by the management of fiduciary duties under ERISA. Violation of fiduciary duties by management could result in liability not only for management but also for the trustee or other fiduciary of an investing ERISA Plan. In addition, if our assets are classified as "plan assets," certain transactions that we might enter into in the ordinary course of our business might constitute "prohibited transactions" under ERISA and the Code.

Under Code Section 408(i), as amended by the Tax Reform Act of 1986, IRA trustees must report the fair market value of investments to IRA holders by January 31 of each year. The Service has not yet promulgated regulations defining appropriate methods for the determination of fair market value for this purpose. In addition, the assets of an ERISA Plan or Keogh Plan must be valued at their "current value" as of the close of the plan's fiscal year in order to comply with certain reporting obligations under ERISA and the Code. For purposes of such requirements, "current value" means fair market value where available. Otherwise, current value means the fair value as determined in good faith under the terms of the plan by a trustee or other named fiduciary, assuming an orderly liquidation at the time of the determination. We do not have an obligation under ERISA or the Code with respect to such reports or valuation although management will use good faith efforts to assist fiduciaries with their valuation reports. There can be no assurance, however, that any value so established (i) could or will actually be realized by the IRA, ERISA Plan or Keogh Plan upon sale of the Shares or upon liquidation of us, or (ii) will comply with the ERISA or Code requirements.

The income earned by a qualified pension, profit sharing or stock bonus plan (collectively, "Qualified Plan") and by an individual retirement account ("IRA") is generally exempt from taxation. However, if a Qualified Plan or IRA earns "unrelated business taxable income" ("UBTI"), this income will be subject to tax to the extent it exceeds $1,000 during any fiscal year. The amount of unrelated business taxable income in excess of $1,000 in any fiscal year will be taxed at rates up to 36%. In addition, such unrelated business taxable income may result in a tax preference, which may be subject to the alternative minimum tax. It is anticipated that income and gain from an investment in the Shares will not be taxed as UBTI to tax exempt shareholders, because they are participating only as passive financing sources.

INVESTOR ELIGIBILITY STANDARDS

The Shares will be sold only to a person who is not an accredited investor if the aggregate purchase price paid by such person is no more than 10% of the greater of such person's annual income or net worth, not including the value of his primary residence, as calculated under Rule 501 of Regulation D promulgated under Section 4(a)(2) of the Securities Act of 1933, as amended. In the case of sales to fiduciary accounts (Keogh Plans, Individual Retirement Accounts (IRAs) and Qualified Pension/Profit Sharing Plans or Trusts), the above suitability standards must be met by the fiduciary account, the beneficiary of the fiduciary account, or by the donor who directly or indirectly supplies the funds for the purchase of Shares. Investor suitability standards in certain states may be higher than those described in this Offering Circular. These standards represent minimum suitability requirements for prospective investors, and the satisfaction of such standards does not necessarily mean that an investment in the Company is suitable for such persons.

Each investor must represent in writing that he/she/it meets the applicable requirements set forth above and in the Subscription Agreement, including, among other things, that (i) he/she/it is purchasing the Shares for his/her/its own account and (ii) he/she/it has such knowledge and experience in financial and business matters that he/she/it is capable of evaluating without outside assistance the merits and risks of investing in the Shares, or he/she/it and his/her/its purchaser representative together have such knowledge and experience that they are capable of evaluating the merits and risks of investing in the Shares. Transferees of Shares will be required to meet the above suitability standards.

WHERE YOU CAN FIND MORE INFORMATION

The Company has filed a Regulation A Offering Statement on Form 1-A with the SEC under the Securities Act of 1933 with respect to the shares of the Class A Common Stock offered hereby. This Offering Circular, which constitutes a part of the Offering Statement, does not contain all of the information set forth in the Offering Statement or the exhibits and schedules filed therewith. For further information about us and the Class A Common Stock offered hereby, we refer you to the Offering Statement and the exhibits and schedules filed therewith. Statements contained in this Offering Circular regarding the contents of any contract or other document that is filed as an exhibit to the Offering Statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the Offering Statement. Upon the completion of this Offering, the Company will be required to file periodic reports and other information with the SEC pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the SEC's Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet website that contains reports, proxy statements and other information about issuers, including the Company, that file electronically with the SEC. The address of this site is www.sec.gov.

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