As submitted confidentially to the Securities and Exchange Commission on November 15, 2017.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
under
The Securities Act of 1933

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**47-1178401**
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification No.)

501 Fifth Avenue, Suite 1404
New York, NY 10017
917-289-1117

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Tsontcho Ianchulev
Chief Executive Officer
501 Fifth Avenue, Suite 1404
New York, NY 10017
917-289-1117

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Barry I. Grossman, Esq. **Benjamin S. Reichel, Esq.** **Ellenoff Grossman & Schole LLP** **1345 Avenue of the Americas** **New York, New York 10105** **Phone: (212) 370-1300** **Fax: (212) 370-7889**	**Michael D. Maline, Esq.** **Seo Salimi, Esq.** **Goodwin Procter LLP** **620 Eighth Avenue** **New York, New York 10018** **Phone: (212) 813-8800** **Fax: (212) 656-1546**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If delivery of the Prospectus is expected to be made pursuant to Rule 434, check the following box. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	**Proposed Maximum Aggregate Offering Price[(1)]**	**Amount of Registration Fee**
Common Stock, par value $0.0001 per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee under Rule 457(o) of the Securities Act of 1933, as amended (the "Securities Act"). Includes shares of our common stock that the underwriters have the option to purchase to cover over-allotments, if any.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion. Dated , 2017.

Preliminary Prospectus

Shares

COMMON STOCK

We are offering shares of our common stock. This is our initial public offering and no public market currently exists for our shares. We anticipate that the initial public offering price of our common stock will be between $ and $ per share.

We intend to apply to list our common stock on The NASDAQ Capital Market under the symbol "EYEN."

We are an "emerging growth company" under the federal securities laws and are therefore subject to reduced public company reporting requirements.

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

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 10.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriting" for additional information regarding underwriting compensation.

We have granted the underwriters the right to purchase up to an additional shares of common stock to cover over-allotments, if any.

The underwriters expect to deliver the shares of common stock to purchasers on or about , 2017.

Ladenburg Thalmann **Roth Capital Partners**

, 2017

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You should rely only on the information contained in this prospectus or contained in any free writing prospectus prepared by or on behalf of us. Neither we nor the underwriters have authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any related free writing prospectus. This prospectus is an offer to sell only the shares offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of its delivery. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including , 2018 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

For investors outside the U.S.: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the U.S. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read the entire prospectus carefully, including the section entitled "Risk Factors" and our financial statements and the related notes included elsewhere in this prospectus before making an investment decision to purchase shares of our common stock.

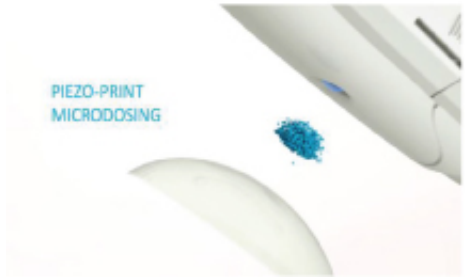
In this prospectus, unless we indicate otherwise or the context requires, references to the "Company," "Eyenovia," "we," "our," "ours," and "us" refer to Eyenovia, Inc. The following summary is qualified in its entirety by the more detailed information and financial statements and notes thereto included elsewhere in this prospectus.

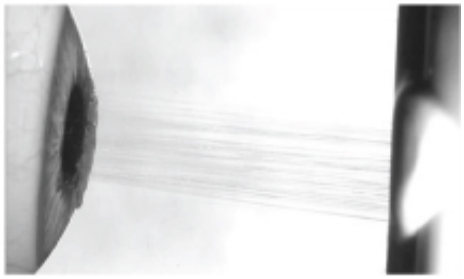
Our Business

Overview

We are a clinical stage biopharmaceutical company developing a pipeline of ophthalmology products utilizing our patented piezo-print technology to deliver micro-doses (6–8 µL) of active pharmaceutical ingredients, or micro-therapeutics, topically to the eye. This micro-dosing technology has the potential to replace traditional macro-dosing applications (e.g. conventional eye droppers that deliver 30–50 µL) that routinely overdose or under-dose when used in the topical administration of ophthalmic therapeutics. We believe our micro-therapeutic product candidates may be able to achieve similar pharmacologic effects as traditional macro-dosing applications while reducing the adverse effects associated with these techniques. We have received written Food and Drug Administration, or FDA, feedback indicating that we can proceed to Phase III clinical trials for two of our lead programs: MicroProst, a novel micro-therapeutic latanoprost formulation for chronic angle closure glaucoma, or CACG, an indication with no FDA-approved drug treatments; and MicroStat, a fixed combination of micro-therapeutic phenylephrine-tropicamide formulation for mydriasis, also known as pupil dilation for use in eye exams. MicroTears, our over-the-counter, or OTC, product candidate for dry eye, will not require Phase III clinical trials, and we plan to proceed with registration activities.

We have completed two Phase II clinical trials, treating more than 110 subjects, with results published in peer-reviewed literature. Applying multiple front-of-the-eye (the area in front of the lens) formulations in subjects for mydriasis, our piezo-print technology delivered microliter precision at the volume of the eye's natural tear film capacity of 6–8 µL, which reduced ocular and systemic drug and preservative exposure when compared to eye drops, resulting in comparable efficacy with fewer side effects. We believe that these clinical trials support our advancement into late stage clinical trials utilizing the 505(b)(2) pathway. We intend to use this pathway for future clinical trials in new indications with significant unmet needs.





Our Solution

The eye holds just 6–8 µL of fluid, yet conventional eye droppers deliver 30–50 µL. This results in ocular toxicity that is unnecessary due to ocular overexposure to drug ingredients and preservatives. Our high precision micro-therapeutic technology delivers doses of 6–8 µL, directly coating the corneal surface rather than the conjunctiva, which reduces collateral tissue exposure and focuses on the cornea where 80% of intraocular drug penetration occurs. We believe that micro-therapeutics may reduce drug and toxic preservative exposure by more than 75%, thus reducing ocular irritation, resulting in potentially gentler treatments without compromising the desired clinical effect. Our micro-therapeutic approach also reduces waste associated with conventional macro-dose drops — a problem that has been highlighted by recently introduced legislation in the U.S. Senate to address this specific concern.

We believe that we are the only company with clinical stage technology for targeted micro-dosing of ophthalmic investigational therapies. Our solution is based on piezo-print technology, which is also used for pixel-sharp high-precision inkjet printing. The technology is optimized for and applied in ophthalmic delivery to achieve micro-dosing that is many times more precise than conventional eye droppers. In addition, as an electronic system, we are able to track when patients administer their medications and deliver this information to patients and physicians via Bluetooth connectivity. This enables physicians to track compliance and make decisions regarding therapeutic regimens with knowledge of patient compliance.

Our micro-dosing platform technology aims to address the following issues associated with eye drop-based therapies:

- Improper dosing, administration and waste of medication;

- Side effects associated with conventional macro-dose therapies; and
- Potential for toxicity.

In the ophthalmology space, we believe that our micro-therapeutics will come with first-in-class smart sensing technology for mobile e-health applications and compliance monitoring, which will be standard with all of our smart cartridges. This technology has the potential to improve compliance and chronic disease management by tracking each time a patient administers treatment, empowering patients and physicians with access to dynamic, real time monitoring and compliance data for a more intelligent and personalized therapeutic paradigm.

Our micro-therapeutic solution has been tested in preclinical models and clinical trials and has been shown to provide many advantages over the current administrations. Key advantages include:

- Dose reduction: Our micro-droplet delivery technology achieves precise volumetric control at the microliter level to deliver 6–8 µL, which is the physiologic capacity of the tear film compared to the dropper pipette macro-dose of 30–50 µL which results in overdosing, ocular toxicity and systemic leaching into the plasma.
- Targeted dose instillation: Our piezo-print technology allows for targeted delivery to the ocular surface and cornea, avoiding the conjunctival cul-de-sac. The micro-jet created by the piezo-electric vibrations is columnated and focused to provide accurate delivery to the corneal surface where the majority of ocular penetration occurs. Additionally, our device includes an LED targeting mechanism to allow proper positioning and objective alignment.
- Speed of delivery: Similar to high-precision ink-jet printing that can deliver pixel-sharp precision ink jet printing, we use piezo-electric dispensation. Unlike a simple aerosolized mechanism, our patented piezo-printing technology achieves micro-droplet ejection control that creates a fast and targeted micro-jet delivery. We can deliver our micro-therapeutics to the ocular surface in less than 80 milliseconds beating the eye's 100 millisecond blink reflex.
- Smart electronics: Our smart electronics and mobile e-health technology are designed to track when a patient administers treatment. This enables physicians to monitor patient compliance accurately. We believe this technology will improve compliance and chronic disease management by empowering patients and physicians with access to dynamic, real time monitoring and compliance data for a more intelligent and personalized therapeutic paradigm.

Our Pipeline

The following summarizes our product pipeline and expected milestones:

Product Candidate	Indication	Next Expected Milestones
MicroProst	Chronic Angle Closure Glaucoma	Phase III IND H2 2018
MicroStat	Mydriasis (Pupil Dilation)	Phase III IND H2 2018
MicroTears	Dry Eye	OTC Registration H1 2019
MicroPine	Myopia (Near Sightedness)	Phase III IND H1 2019

MicroProst

MicroProst is our proprietary latanoprost prostaglandin micro-formulation product candidate being developed as a first-line indication for CACG. Currently, there are no FDA-approved therapies for CACG, which accounts for 10% and 50% of all glaucoma diagnoses in the U.S. and China, respectively. We believe that the market exceeds $700 million in the U.S. alone.

Phase III Clinical Development Program

Subsequent to the completion of our Phase II clinical trials, we met with the FDA to discuss our Phase III plans for MicroProst. The FDA outlined the necessary clinical trials for approval, and we are preparing to initiate a Phase III registration program, relying on the 505(b)(2) pathway, for a first-line

therapeutic indication in CACG for MicroProst. If approved, MicroProst will be the first FDA-approved treatment for CACG. Our targeted piezo-print technology will provide micro-dosing (6–8 µL) of prostaglandin latanoprost directly to the ocular surface of the cornea, which is the site of the highest intraocular penetration. We believe MicroProst will achieve similar clinical activity without the adverse effects seen with conventional drops, which overdose the eye with potentially harmful preservatives and active pharmaceutical ingredient, or API. This could provide additional opportunities for us to pursue follow-on expanded indications of MicroProst, such as for the treatment of open-angle glaucoma, where non-micro-therapeutic latanoprost is currently the primary therapeutic modality.

The MicroProst Phase III program will consist of two randomized controlled clinical trials in CACG with a 3-month primary end-point consisting of a reduction in intraocular pressure, or IOP, and follow-up for six months. We plan to commence the clinical trial in the second half of 2018, subject to a pre-investigational new drug application meeting with the FDA in early 2018, and estimate 200 patients per clinical trial. If the primary objectives of our Phase III program are met, we plan to submit a New Drug Application, or NDA, for marketing approval of MicroProst for the treatment of CACG in the U.S. We entered into a licensing partnership for our MicroProst program with Senju Pharmaceuticals for Asia, including China where CACG accounts for up to 50% of all glaucoma.

MicroStat

MicroStat is the potentially first-in-class fixed combination micro-formulation product candidate for mydriasis (eye dilation) intended to facilitate office-based eye examinations to serve the over 80 million dilated retina eye exams performed each year in the U.S. MicroStat has been designed to achieve adequate pupil dilation while reducing unintended effects of conventional mydriatic agents. We believe the market exceeds $150 million in the U.S. alone.

Phase III Clinical Development Program

Based on our Phase II clinical trials and subsequent FDA feedback, we are proceeding towards the initiation of the Phase III clinical trials of a fixed-combination, micro-formulation of phenylephrine 2.5% and tropicamide 1% for mydriasis.

The MicroStat program will consist of two Phase III randomized, controlled clinical trials to demonstrate pharmacologic dilation of our fixed combination micro-formulation versus drops of individual components of phenylephrine and tropicamide with the primary endpoint of pupil change from baseline. We anticipate enrolling 100 patients per clinical trial, and intend to commence the clinical trials in the second half of 2018. If the primary objectives of our Phase III program are met, we plan to submit an NDA to the FDA for marketing approval in the U.S. Outside of the U.S., we have entered into a licensing partnership for MicroStat with Senju Pharmaceuticals for commercialization in Asia, including China, Japan and India.

MicroTears

MicroTears is a differentiated micro-droplet ocular surface tear replenishment product candidate for the $2 billion OTC artificial tear market. Our piezo-technology enables accurate delivery directly to the ocular surface, which we believe enhances its effectiveness. The lower volume of MicroTears will also lower the incidents of droplet overflow. While no FDA studies are required for registration of a monograph formulation, we expect to conduct multiple Phase IV post-marketing studies to demonstrate the benefits of MicroTears. We plan to complete formulation and manufacturing scale-up activities for an expected market introduction in mid-to-late 2019.

Other Programs

In addition to MicroProst, MicroStat and MicroTears, we are developing an expanded pipeline of therapeutic product candidates and are preparing them for late-stage clinical trials. The first pipeline opportunity is MicroPine, which is a micro-therapeutic formulation of atropine to target myopia (or near sightedness) progression. Clinical trials conducted to date, as well as a recent technology analysis and review by the American Academy of Ophthalmology, indicate Level 1 (highest) evidence of efficacy for the role of

low dose atropine for myopia progression. To date, no therapy has been possible due to side effects associated with existing macro-dosed drop formulations in the pediatric population using atropine. We have begun development activities for MicroPine with a planned Phase III clinical trial expected to be initiated in 2019.

Our Strategy

Our goal is to become a leading biopharmaceutical company focused on developing and commercializing novel therapies for front-of-the-eye conditions by utilizing our micro-therapeutic piezo-print technology. The key elements of our strategy to achieve this goal are:

Establish a portfolio of first-in-class piezo-print micro-therapeutic products for front-of-the-eye treatments through the 505(b)(2) pathway with the FDA. We are initially focused on developing technology utilizing therapeutic compounds already well established in the topical treatment of ophthalmic indications. We believe that the 505(b)(2) registration pathway, which reduces development risk compared to new molecular entity programs by working with known compounds with well-established safety and efficacy profiles, will be available for our initial development pipeline. We believe our pipeline of patented micro-therapeutic product candidates will be highly differentiated by our improved tolerability and enhanced compliance profile and our late-stage development programs could lead to NDA submissions in novel indications where the products can have unique dosing and therapeutic profiles. We believe that this could lead to favorable pricing and reimbursement, and a reduced risk of generic substitution.

Improve clinical outcomes and patient experiences while providing an improved tolerability profile with our micro-therapeutics. We believe our piezo-print platform will allow for high precision targeted micro-dosing for front-of-the-eye treatments, while eliminating ophthalmic over-dosing and reducing ocular exposure to toxic preservatives and pharmacologic ingredients by over 75% compared to conventional eye drop delivery mechanisms. Our clinical trials have demonstrated equivalent biologic activity, improved side effect profile and enhanced patient experience of our micro-therapeutic approach as compared to conventional eye drops.

Leverage our electronic, smartphone-enabled "e-health" technology to introduce and develop patient-specific compliance monitoring program. Our mobile e-health technology and smart cartridges are designed to track when a patient administers treatments, allowing physicians to track patient compliance accurately. We believe this may enhance patient compliance and improve compliance monitoring by empowering patients and physicians with access to dynamic, real-time monitoring and compliance data for a more intelligent, informed and personalized therapeutic paradigm.

Develop micro-therapeutic treatments for other ophthalmic diseases independently or in collaboration with third parties. Our piezo-print technology is also suitable for new molecular entities. Leveraging our existing platform technology, we plan to continue developing other micro-therapeutic product candidates for front-of-the-eye diseases that can be administered using our piezo-print technology platform with mobile e-health technology and smart cartridges either independently or through strategic partnerships with third parties. We have entered into an exclusive agreement with Senju Pharmaceuticals, a leading ophthalmology company in Japan, for the Asian development and commercial rights of our therapies and technology.

Develop solutions for ophthalmic conditions with high unmet needs and no approved therapy. We will target chronic ophthalmic conditions with a high unmet medical need. By leveraging our piezo-print micro-dosing technology, we aim to reach conditions where there are no approved therapies. For example, our MicroPine program which is a micro-formulation of atropine, is intended to slow myopia progression in the pediatric population. However, there are currently no therapies on the market due to side effects associated with traditional macro-dosing drop formulations.

Our Team

Our management team is a critical component to the execution of our overall strategy and business model. We have assembled a team with significant experience in translational science, drug evaluation, clinical development, regulatory affairs and business development. Our management team is led by our

Chief Executive Officer, Dr. Tsontcho Ianchulev, who has over 15 years of experience in public health, life-science and medical technology. He is a physician-executive and public health expert who has been at the core of developing medical products and technologies which have transformed the ophthalmic field and impacted medical care for thousands of patients each year. His intellectual property was a core asset to WaveTec's (acquired by Alcon) technology for intraoperative aberrometry. He is currently a Professor of Ophthalmology at the New York Eye and Ear Infirmary and sits on the Boards of Iantech Medical, Kurobe Pharmaceuticals and The American Society of Cataract and Refractive Surgery Foundation. Dr. Ianchulev spent five years at Genentech where he headed the ophthalmology research group and directed the development and FDA approval of Lucentis, a successful specialty biologic in the field of ophthalmology with more than $4 billion of annual sales in 2015. Most recently, he headed all clinical development of Transcend Medical's (acquired by Alcon) micro-stent for glaucoma. Dr. Ianchulev's clinical experience, combined with development and commercial work in both biopharmaceuticals and medical devices make him ideally suited to lead Eyenovia. Dr. Ianchulev is a graduate of Harvard Medical School and has an MPH degree from the Harvard School of Public Health.

In addition to Dr. Ianchulev, the management team has other professionals with deep engineering, clinical trial, regulatory and commercial experience in ophthalmology. Our management team is supported by our Board of Directors, which has extensive professional experience in strategic development, executive, operational and financial leadership in the pharmaceutical and healthcare industries, including several successful ophthalmology companies.

Risks Associated with our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

- We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and may never achieve or maintain profitability;
- Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability;
- We may not be able to develop marketable products utilizing our technology and we may not be able to identify and successfully implement an alternative product development strategy;
- Ophthalmic micro-therapeutic research and development is a highly uncertain undertaking. Our development efforts may be delayed for any number of reasons, in which case potential marketing approval or commercialization of our proprietary technology could be delayed or prevented;
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue would be materially impaired;
- If the market opportunities for our future product candidates are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer;
- The commercial success of our product candidates will depend on the degree of market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community; and
- We have material weaknesses in our internal control over financial reporting. In addition, because of our status as an emerging growth company, our independent registered public accountant is not required to provide an attestation report as to our internal control over financial reporting for the foreseeable future.

Corporate Information

We were organized as a corporation under the laws of the State of Florida on March 12, 2014 under the name "PGP Holdings V, Inc." On May 5, 2014, we changed our name to Eyenovia, Inc. On October 6, 2014, we reincorporated in the State of Delaware by merging into Eyenovia, Inc., a Delaware corporation. Our principal executive office is located at 501 Fifth Avenue, Suite 1404, New York, NY 10017, and our phone number is 917-289-1117. Our website is *http://www.eyenovialab.com*. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and only two years of selected financial data in this prospectus;
- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. For example, we intend to take advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced reporting burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

The Offering

Common stock to be offered by us	shares
Common stock to be outstanding immediately following this offering	shares
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from the sale of our common stock sold in this offering will be approximately $ million, based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds from this offering to (i) complete Phase III clinical trials for MicroProst and MicroStat, (ii) complete MicroTears registration activities, (iii) complete scale-up engineering and manufacturing for pivotal trials and FDA approval, (iv) complete formulation work for each development program and (iv) for general corporate purposes, including working capital. See the section entitled "Use of Proceeds."
Risk factors	You should read the section entitled "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq Capital Market symbol	"EYEN"

The number of shares of our common stock to be outstanding following this offering is based on 9,624,488 shares of our common stock outstanding as of September 30, 2017 and excludes:

- 6,316,534 shares of our common stock underlying outstanding options to purchase common stock with a weighted average exercise price of $0.45; and
- 183,466 shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan.

Unless otherwise noted, the information in this prospectus reflects and assumes the following:

- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 17,400,772 shares of our common stock effective immediately prior to the completion of this offering;
- no exercise of outstanding options; and
- no exercise of the underwriters' over-allotment option to purchase additional shares.

Selected Financial Data

The following summary financial data for the years ended December 31, 2016 and December 31, 2015 and the balance sheet data as of December 31, 2016 and December 31, 2015 have been derived from our audited financial statements appearing elsewhere in this prospectus. The summary financial data as of September 30, 2017 and for the nine months ended September 30, 2017 and September 30, 2016 have been derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair statement of such financial data. You should read this data together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information under the captions "Risk Factors," "Capitalization," "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and our operating results for the nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2017 or any other interim periods or any future year or period.

	Nine Months Ended September 30,		Year Ended, December 31,	
	2017	2016	2016	2015
	(unaudited)			
Statement of Operations Data:				
Operating Expenses:				
Research and development	$ 2,125,993	$ 1,985,536	$ 2,966,165	$ 2,783,200
General and administrative	842,959	391,945	568,775	1,486,401
Total Operating Expenses	2,968,952	2,377,481	3,534,940	4,269,601
Loss from Operations	(2,968,952)	(2,377,481)	(3,534,940)	(4,269,601)
Other Income:				
Interest income	1,396	921	1,497	2,412
Total Other Income	1,396	921	1,497	2,412
Net Loss	$(2,967,556)	$(2,376,560)	$(3,533,443)	$(4,267,189)
Net Loss Per Share–Basic and Diluted	$ (0.35)	$ (0.28)	$ (0.42)	$ (0.50)
Weighted Average Number of Common Shares Outstanding–Basic and Diluted				
Diluted	8,514,906	8,500,000	8,500,000	8,500,000

	As of September 30, 2017	As of December 31,	
		2016	2015
	(unaudited)		
Balance Sheet Data:			
Cash	$ 7,406,034	$3,387,288	$2,492,611
Working capital	$ 6,946,806	$2,965,889	$2,385,621
Total assets	$ 7,689,230	$3,432,815	$2,818,319
Total liabilities	$ 7,003,720	$ 423,734	$ 419,823
Total stockholders' equity	$ 685,510	$3,009,081	$2,398,496

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred operating losses of $17.1 million since inception, have not generated any product sales revenue and have not achieved profitable operations. Our net losses were $3.5 million for the year ended December 31, 2016 and $3.0 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of $17.1 million. We expect to continue to incur substantial losses in future periods while we continue to test and prepare our product candidates for the market. It could be several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned preclinical and clinical development of our product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek marketing approvals for our current and future product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- implement operational, financial and management systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

Even if we are able to generate revenues from the sale of our potential products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. In addition, because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company which commenced active operations in 2014. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and developing our product candidates. We have not yet demonstrated our ability to successfully complete a Phase III program, obtain regulatory approval, develop an in-house manufacturing facility, manufacture a

commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a product development focus to a company capable of supporting commercial and manufacturing activities. We may not be successful in such a transition.

Even if this offering is successful, we will need to raise additional funding in order to receive approval for our product candidates. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.

We may require substantial additional funding in addition to the net proceeds of the offering to fund completion of our research and development activities. We also may require substantial funding to fund our commercialization efforts, operating expenses and other activities. If additional funds are not available, we may need to significantly scale back or cease our operations.

We will require substantial funds to discover, develop, protect and conduct research and development for our product candidates, including preclinical testing and clinical trials of any of our product candidates, and to manufacture and market any such product that may be approved for commercial sale. Even if we are successful in raising additional capital, such funds may prove to be insufficient for these activities. Our financing needs may change substantially because of research and development costs, competition, clinical trials and costs arising from additional regulatory approvals. We may not succeed in raising needed additional funds. The timing of our need for additional funds will depend on a number of factors, which factors are difficult to predict or may be outside of our control, including:

- the resources, time and costs required to initiate and complete our research and development, to initiate and complete preclinical studies and clinical trials and to obtain regulatory approvals for our product candidates;
- progress in our research and development programs;
- the timing, receipt and amount of milestone, royalty and other payments from future collaborators, if any; and
- costs necessary to protect our intellectual property.

If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our operating plan. Additional funds may not be available to us on acceptable terms, or at all, when needed.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

Until such time as we can generate substantial product revenues, we may attempt to finance our cash needs through equity offerings, debt financings, government and/or other third-party grants or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our investors' ownership interest will be diluted. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more clinical research or development programs, which would adversely impact potential revenues, results of operations and financial condition.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

If we are unable to use carryforward tax losses or benefit from favorable tax legislation to reduce our taxes, our business, results of operations and financial condition may be adversely affected.

We have incurred significant net operating losses since our inception in July 2014. As of December 31, 2016, we had federal net operating loss carry-forwards of approximately $7.2 million. State net operating losses are not materially different from the federal net operating losses. If we are unable to use carryforward tax losses to reduce our future taxable basis for corporate tax purposes, our business, results of operations and financial condition may be adversely affected.

Net operating loss and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The federal and state income tax returns are generally subject to tax examinations. To the extent we have tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. Any unfavorable tax adjustment could have a significant impact on our results of operations and future cash flows. Furthermore, if the U.S. government decides to eliminate, or reduce the scope or the rate of any tax benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

RISKS RELATED TO DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

We may not be able to develop marketable products utilizing our technology and we may not be able to identify and successfully implement an alternative product development strategy.

The approach we have adopted to discover and develop product candidates is new and may never lead to marketable products. We have concentrated our efforts on developing therapeutic product candidates utilizing new advanced technology for drug delivery. To our knowledge, no person or company has developed any therapeutic product utilizing the same technology and no such ophthalmic micro-therapeutic product has been approved for marketing to date. We are leading a new field of ophthalmic micro-therapeutic research and development and the scientific discoveries that form the basis for our efforts to develop products are relatively new. The scientific evidence to support the feasibility of developing such products and treatments based on these discoveries is both preliminary and limited. Our focus solely on developing products utilizing our proprietary technology as opposed to more proven technology increases the risks associated with the offering. If we are unsuccessful in developing product candidates utilizing our technology, we may be required to change the scope and direction of our product development activities. If we are not able to identify and successfully implement an alternative product development strategy, our business may fail.

Ophthalmic micro-therapeutic research and development is a highly uncertain undertaking. Our development efforts may be delayed for any number of reasons, in which case potential marketing approval or commercialization of our proprietary technology could be delayed or prevented.

Our research and development activities to develop ophthalmic micro-therapeutics utilizing our proprietary technology may be impeded due to scientific or technological difficulties or our lack of complete understanding of the challenges. Our research and development activities may not give rise to a marketable product and we may not succeed in developing a marketable product in a timely manner or in accordance with our estimated budgets. Even if we are successful in developing such products, there is no certainty that our products, when developed, will be found to be sufficiently effective and safe for use to receive regulatory approval for marketing, which would adversely impact our potential revenues, results of operations and financial condition.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue would be materially impaired.

Our business depends on the success of our lead research and development programs which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. In addition, we do not have any products that have gained regulatory approval. Our business and future success depends on our ability to obtain regulatory approval of and then successfully commercialize our lead product candidates. We are currently preparing for Phase III clinical trials and our ability to develop, obtain regulatory approval for, and successfully commercialize, products will depend on several factors, including the following:

- further ascertaining the FDA's expectations with respect to the nonclinical and clinical testing requirements across the development programs;
- successful completion of our current clinical trials or other clinical trials, which will depend substantially upon the satisfactory performance of third-party contractors;
- successful achievement of the objectives of planned clinical trials, including manufacturability qualification of devices;
- receipt of marketing approvals from the FDA, and similar regulatory authorities outside the U.S.;
- establishing commercial manufacturing and supply arrangements;
- establishing a manufacturing and commercial infrastructure;
- acceptance of the products by patients, the medical community and third-party payors;
- establishing market share while competing with other therapies;
- successfully executing our pricing and reimbursement strategy;
- a continued acceptable safety and adverse event profile of the products following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering the products.

Our business strategy is to develop several pipeline product candidates over the next approximately two to three years which will require additional clinical and nonclinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. If we are unable to develop or receive marketing approval in a timely manner or at all, we could experience significant delays or an inability to commercialize the product, which would materially and adversely affect our business, financial condition and results of operations.

We may encounter substantial delays in or failure of our clinical trials.

If the clinical trials that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market our prospective product candidates.

We may experience delays in any phase of the development and commercial launch of product candidates, including during research and development and clinical trials. Implementing a clinical trial is time-consuming and expensive, and the outcome of any clinical trial is uncertain. The completion of any of these clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards, or IRB, the European Union regulatory authorities, or the European Medicines Agency, and national authorities, or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on hold;
- patients do not enroll in a clinical trial or results from patients are not received at the expected rate;
- patients discontinue participation in a clinical trial prior to the scheduled endpoint set forth in the clinical protocol at a higher than expected rate, especially if such discontinuations interfere with our ability to assess the efficacy of our drug candidate;
- patients experience adverse events from our treatment;
- patients get hurt during a clinical trial for a variety of reasons that may or may not be related to our product candidates, including the advanced stage of their disease and other medical problems;
- third-party clinical investigators do not perform the clinical trials in accordance with the anticipated schedule or consistent with the clinical trial protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- enrollment and sample size of our clinical trials may be substantially different than estimated which may lead to longer timelines and larger expenses;
- third-party clinical investigators engage in activities that, even if not directly associated with our clinical trials, result in their debarment, loss of licensure, or other legal or regulatory sanction;
- regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the clinical trials;
- changes in governmental regulations or administrative actions;
- the interim results of the clinical trial, if any, are inconclusive or negative; and
- the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety.

Our dependence upon clinical trials in developing product candidates may impede them from reaching advanced stages of development, and might prevent all or part of our commercial operations. To date, the aforementioned situations regarding potential delays in research and development activities and clinical trials have yet to occur in a manner which adversely affects our research and development activities.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

Human clinical trials are expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies, we expect that such human clinical trials will require extensive research and development and have substantial manufacturing and processing costs. Accordingly, our clinical trial costs could be significantly higher than other conventional therapeutic technologies or drug products.

We may find it difficult to enroll an adequate number of patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, the design of the clinical protocol,

the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. Any inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may also result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

In addition, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays in the enrollment for any clinical trial of our product candidates will increase our costs, slow down our product development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon our development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any serious adverse or undesirable side effects identified during the development of our product candidates, could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. In addition, if any of our product candidates receive regulatory approval and we or others later identify undesirable adverse effects caused by the product, we could face one or more of the following consequences:

- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication, or other safety labeling changes;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or a REMS;
- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may seize the product;
- we may be required to change the way that the product is administered, or conduct additional clinical trials or we may need to recall the product;
- we may be subject to litigation or product liability claims fines, injunctions or criminal penalties; and
- our reputation may suffer.

If the market opportunities for our future product candidates are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer.

We are currently focusing our research and product development efforts on our glaucoma, pupil dilation and dry eye products. Our understanding of both the number of people who have these needs, as well as the subset of people who have the potential to benefit from our product candidates, are based on estimates in published literature. While we believe these estimates are reasonable, they may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of glaucoma and dry eyes and the need for pupil dilation. The number of patients in the U.S., the European Union and elsewhere may

turn out to be lower than expected or these patients may not be otherwise amenable to our product candidates or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

The commercial success of our product candidates will depend on the degree of market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community.

Even if we receive regulatory approval to market our product candidates, our product candidates may not gain market acceptance upon their commercial introduction, which could prevent us from becoming profitable.

We may have difficulties convincing the medical community, third-party payors and consumers to accept and use any of our product candidates that may be approved for commercialization in the future. Other factors that we believe will affect market acceptance of our product candidates include:

- the timing of our receipt of any marketing approvals, the terms of any approvals and the countries in which approvals are obtained;
- safety, efficacy and ease of administration of our product candidates;
- the success of physician education programs;
- the availability of government and third-party payor reimbursement;
- the pricing of our product candidates, particularly as compared to alternative treatment methods and medications;
- the extent to which alternative treatment methods and medications are more readily available as compared to the availability of any product candidates that we may develop in the future; and
- the prevalence and severity of any adverse effects.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The specialty pharma market is highly competitive. If we are unable to compete effectively with existing products, new treatment methods and new technologies, we may be unable to commercialize any therapeutic products that we may develop in the future.

The specialty pharma market is subject to rapid technological change and is significantly affected by existing rival products and medical procedures, new product introductions and the market activities of other participants. Pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations may pursue the research and development of technologies, drugs or other therapeutic products for the treatment of some or of the diseases we are targeting. We may also face competition from products which have already been approved and accepted by the medical community for the treatment of these same indications.

As a result of any of the foregoing factors, our competitors may develop or commercialize products with significant advantages over any therapeutic products that we may develop. If our competitors are more successful in commercializing their products than we are, their success could adversely affect our competitive position and harm our business prospects.

Even if we are able to commercialize any of the product candidates that we may develop, the product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize our therapeutic products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations.

However, any therapeutic products we may develop could become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the U.S. or other jurisdictions, which could adversely affect the profitability of our business.

The regulations that govern pricing for new medical products vary widely from country to country. As a result, we might obtain regulatory approval for a product in a particular country, but then be subjected to pricing regulations in that country that delay the commercial launch of the product and negatively impact the revenues able to be generated from the sale of the product in that country. In addition, our ability to commercialize any approved products successfully will depend in part on the extent to which reimbursement for these products will be available from government health administration authorities, private health insurers and other organizations. Even if we succeed in bringing one or more therapeutic products to market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow their sale on a competitive basis. If the price we are able to charge for therapeutic products is inadequate in light of our development and other costs, our profitability could be adversely affected.

If we fail to establish an effective distribution process our business may be adversely affected.

We have limited experience in the sale, marketing and distribution of drug products. To achieve commercial success for the product candidates for which we obtain marketing approval, we will need to establish and maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. Failure to secure contracts with wholesalers could negatively impact the distribution of our potential products, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of our potential products may be delayed or severely compromised and our results of operations may be harmed.

We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We are exposed to the risk of claims seeking monetary damages being filed against us for loss or harm suffered by participants of our clinical trials or for loss or harm suffered by users of any drug that may receive approval for commercialization in the future. In either event, the FDA or the regulatory authorities of other countries or regions may commence investigations of the safety and effectiveness of any such clinical trial or commercialized drug, the manufacturing processes and facilities or marketing programs utilized in respect of any such clinical trial or drug. Such investigations may result in mandatory or voluntary recalls of any commercialized drug or other significant enforcement action such as limiting the indications for which any such drug may be used, or suspension or withdrawal of approval for any such drug. Investigations by the FDA or any other regulatory authority in other countries or regions also could delay or prevent the completion of any of our other clinical development programs. Our insurance policies may not fully cover the risk of loss associated with our operations. In the event that we are required to pay damages for any such claim, we may be forced to seek bankruptcy or to liquidate because our asset and revenue base may be insufficient to satisfy the payment of damages and any insurance that we have obtained or may obtain for product or clinical trial liability may not provide sufficient coverage against potential liabilities.

Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in human clinical trials. We face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

Our insurance policies may not fully cover liabilities that we may incur in the event of a product liability lawsuit. We may need to increase our insurance coverage as we expand our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of any of the product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

RISKS RELATED TO REGULATORY APPROVAL OF OUR PRODUCT CANDIDATES AND OTHER LEGAL COMPLIANCE MATTERS

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we may not be able to commercialize our product candidates, and our ability to generate revenue would be materially impaired.

Any product candidates we may develop will be subject to extensive and burdensome governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and extensive regulatory approval processes are required to be successfully completed in the U.S. and in many foreign jurisdictions such as the European Union and Asia before a new product may be offered and sold in any of these countries or regions. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays.

In the U.S., the product candidates that we intend to develop and market are regulated by the FDA under its drug development and review process. The time required to obtain FDA and other approvals for our product candidates is unpredictable. Before such product candidates can be marketed, our investigational new drug application, or IND, must go into effect permitting the conduct of clinical trials, then we must successfully complete human testing under three phases of clinical trials and FDA must approve our new drug application, or NDA. Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission.

It is possible that FDA will not approve any application that we may submit. It is possible that none of the product candidates that we may develop will obtain the appropriate regulatory approvals necessary for us to commence the offer and sale of such products. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from a particular prospective product.

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

Because we intend to market any therapy that we may develop in jurisdictions in addition to the U.S., such as the European Union, we will likely incur the same costs or more in satisfying foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing and commercialization of our product candidates. Approval by the FDA by itself does not assure approval by regulatory authorities outside the U.S. and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Each of these foreign regulatory approval processes includes all of the risks associated with the FDA approval process, as

well as risks attributable to having to satisfy local regulations within each of these foreign jurisdictions. In addition, any failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Our inability to obtain regulatory approval outside the U.S. may adversely compromise our business prospects.

The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing. We, and any potential collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or our collaborators obtain marketing approval. Thus, if any of our product candidates receive marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, applicable to drug manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion or manufacturing of drug products may lead to investigations by the FDA, Department of Justice and state Attorney General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;

- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

We are subject to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We are subject to U.S. federal and state and also foreign healthcare fraud and abuse laws and regulations. Any finding of our failure to comply with such laws and regulations could have a material adverse effect on our business.

Our operations may be directly or indirectly affected by various broad U.S. federal and state healthcare fraud and abuse laws. These include the U.S. federal anti-kickback statute, which prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of an item or service, for which payment may be made under U.S. federal healthcare programs, such as the Medicare and Medicaid programs. The U.S. federal anti-kickback statute is very broad in scope, and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, many states have adopted laws similar to the U.S. federal anti-kickback statute, and some of these laws are broader than that statute in that their prohibitions are not limited to items or services paid for by a U.S. federal healthcare program but, instead, apply regardless of the source of payment. Violations of these laws could result in fines, imprisonment or exclusion from government-sponsored programs.

Additionally, 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 may expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation 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 plan to market, sell and distribute products for which we obtain marketing approval.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and federal and state laws may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the Health Insurance Portability and Accountability Act, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may affect our ability to commercialize and the prices we obtain for any products that are approved in the U.S. or foreign jurisdictions.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell

or commercialize our product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for clinician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 50% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

With the new Administration and Congress, there may be additional legislative changes, including potentially repeal and replacement of certain provisions of the ACA. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation could provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. For example, it is possible that any repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. The timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects.

Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which any products we may develop are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The costs of prescription pharmaceuticals in the U.S. has also been the subject of considerable discussion in the U.S., and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the U.S. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition may be adversely affected.

We currently rely on a combination of internal manufacturing capacity and third-party manufacturers to produce the product candidates for our clinical trials. If we commence additional clinical trials for any of our product candidates, our ability to complete such clinical trials successfully and to apply for and obtain regulatory approval for marketing will depend upon such third-party manufacturers' consistent production of a product candidate of a defined quality for all phases of clinical testing and for commercial production in accordance with cGMP. Our third party manufacturers' inability to satisfy the chemistry, manufacturing and control concerns of regulatory bodies such as the FDA would either prevent us from completing clinical trials or prevent us from obtaining regulatory approval for marketing, either of which would significantly compromise our business prospects.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the U.S. or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by

the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the U.S., we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the U.S., and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

We may not be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND MANAGING GROWTH

We are highly dependent on the services of our senior management team, including our Chief Executive Officer, Dr. Tsontcho Ianchulev, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team, including our Chief Executive Officer, Dr. Ianchulev. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to

offer. If we are unable to continue to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop drug candidates and our business will be limited and we may experience constraints on our development objectives.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among.

We have limited corporate infrastructure, and may experience difficulties in managing growth.

As of November 15, 2017, we have six employees and rely (and anticipate continuing to rely) heavily on third-party contractors for the provision of professional and other services. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, our ability to commercialize drug candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees, third-party clinical investigators, consultants, licensors and strategic partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, third-party clinical investigators, consultants, licensors and strategic partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a negative impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Our business operations could suffer in the event of system failure. Despite the implementation of security measures, our internal computer systems and those of our contract research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to

occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and further development of our product candidates could be delayed.

We could be impacted by unfavorable results of legal proceedings, including a current litigation seeking to recover damages from us in connection with our purchase of assets from Corinthian Ophthalmic, Inc.

On October 10, 2014, Eyenovia entered into an asset purchase agreement and plan of reorganization with Corinthian Ophthalmic, Inc., or Corinthian, pursuant to which Corinthian sold its intellectual property portfolio and related assets to us for 5,421,102 shares of our Series A preferred stock and 5,000,000 shares of our common stock. A shareholder of Corinthian alleging a fraudulent transfer, is seeking to recover the purchase price of its Corinthian shares and other damages and named our Chief Executive Officer and members of our Board of Directors as defendants in a legal proceeding that has not yet been fully resolved in connection with our asset purchase from Corinthian. We are indemnified by Corinthian in this litigation and Corinthian's applicable insurance policy provides coverage of $10,000,000. As a result, we do not expect to incur a material loss as a result of this litigation.

However, litigation results are inherently unpredictable and regardless of the merit of the allegations, litigations are expensive, time-consuming, disruptive to our operations and distracting to management and may adversely affect our financial condition and operating results.

We have material weaknesses in our internal control over financial reporting. In addition, because of our status as an emerging growth company, our independent registered public accountant is not required to provide an attestation report as to our internal control over financial reporting for the foreseeable future.

We may be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of the registration statement of which this prospectus is a part. This assessment will need to include disclosures of any material weaknesses identified by our management in our internal control over financial reporting. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404.

A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements for the years ended December 31, 2016 and 2015, we determined that our disclosure controls and procedures were ineffective, and that there was a material weakness in our internal controls over financial reporting, due to insufficient segregation of duties in our finance and accounting function because of our limited personnel. We currently have six employees and rely (and anticipate continuing to rely) heavily on third-party contractors for the provision of professional and other services. This resulted in not ensuring appropriate segregation of duties between incompatible functions, and made it more difficult to ensure that financial information is adequately analyzed and reviewed on a timely basis to detect misstatements. These above deficiencies represent a material weakness in our internal control over financial reporting given that they result in a reasonable possibility that a material misstatement to the annual or interim financial statements would not have been prevented or detected.

We have begun evaluating and implementing additional procedures to improve the segregation of duties, however, because of our limited resources we cannot assure that these or other measures will fully remediate the deficiencies or material weakness described above in a timely manner. We intend to address the weakness identified above by increasing the oversight and review procedures of the board of directors with regard to financial reporting, financial processes and procedures and internal control procedures; and when funding is available, hiring additional finance and accounting personnel. Nevertheless, there can be no assurances that we will have enough financial resources to remedy our current material weaknesses and significant deficiencies. If we are unable to remediate the material weakness, or otherwise maintain effective

internal control over financial reporting, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports in a timely manner. We cannot assure you that we have identified all of our existing significant deficiencies and material weaknesses, or that we will not in the future have additional significant deficiencies or material weaknesses.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the recently enacted JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act. We will remain an "emerging growth company" for up to five years, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30th before that time, we would cease to be an "emerging growth company" as of the following December 31st. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future.

Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We have limited clinical trial experience. We may rely upon third parties in conducting our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals for our product candidates. We may rely on third parties for clinical development activities. Any reliance on third parties would reduce our control over these activities but would not relieve us of our responsibilities. For example, we would remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we engage third parties and they do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them, which may delay the affected clinical trial.

We contract with third parties for the manufacture of our product candidates for clinical trials and expect to continue to do so in connection with the potential commercialization of our product candidates and for clinical trials and commercialization of any other product candidates that we develop or may develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We rely on a number of third parties for the supply of parts, formulations, active pharmaceutical ingredients, and other materials required for our manufacturing, research and development activities. If we were unable to reach agreements with these third parties, or if we were unable to maintain contractual relationships with these third parties, our research and development activities would be delayed.

We rely on third parties to provide the materials required for our research and development activities. Obtaining these materials requires various approvals as well as reaching a purchase or commercial

agreement on acceptable terms with the provider of the materials. We may not be able to reach agreements with a sufficient number of suppliers or do so on acceptable terms. If we are unable to reach acceptable agreements with a sufficient number of suppliers of materials, our research and development activities will be delayed and our ability to implement our business plan will be compromised.

Our manufacturing process is a complicated and expensive and it requires months of advance planning. We rely on a limited number of manufacturers for our supply. If we were unable to acquire the necessary amount of deliverables to complete our clinical trials, our progress could be delayed substantially.

Additional potential risks related to reliance on third-party manufacturers include:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of their agreements with us;
- delays in obtaining regulatory approval for our product candidates, if our third-party manufacturers fail to satisfy or comply with regulatory requirements;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible breach of the manufacturing agreement by the third party;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or operator error;
- the failure of the third-party manufacturer to comply with applicable regulatory requirements; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We have no manufacturing capacity or experience and anticipate reliance on third-party manufacturers for the development and commercialization of our product candidates in accordance with manufacturing regulations.

In order to develop product candidates, apply for regulatory approvals and commercialize our product candidates, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. We have no manufacturing experience or resources and must incur significant costs to develop this expertise or rely on third parties to manufacture our product candidates. Manufacturing of the product candidates must comply with the cGMP requirements set forth in FDA's regulations. The manufacturing process for our product candidates is an element of the FDA approval process and we will need to contract with manufacturers who can satisfy the FDA requirements on an ongoing basis before seeking to obtain FDA approval. In addition, if we receive the necessary regulatory approval for any of our product candidates, we also expect to rely on third parties, including our collaborators, to manufacture our products in quantities sufficient for commercial marketing. We may experience difficulty in obtaining adequate and timely manufacturing capacity for clinical trials and commercial needs. If we are unable to obtain or maintain contract manufacturing for our product candidates, or are unable to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our product candidates.

If we, our service providers or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

If we, our service providers, or any third-party manufacturers fail to comply with laws regulating the protection of the environment and health and human safety, we could be subject to enforcement actions and our business prospects could be adversely affected.

Our research and development activities, and the research and development activities of our service providers and third-party manufacturers, may involve the use of hazardous materials and chemicals or the maintenance of various flammable and toxic chemicals. Failure to adequately handle and dispose of these

materials could lead to liabilities for resulting damages, which could be substantial. We also may be subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-home pathogens and the handling of bio-hazardous materials.

If we, our service providers, or any third-party manufacturers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our product candidates. These enforcement actions may include:

- restrictions on, or prohibitions against, marketing our product candidates;
- restrictions on importation of our product candidates;
- suspension of review or refusal to approve new or pending applications;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY AND POTENTIAL LITIGATION

Our success depends on our ability to protect our intellectual property and proprietary technology.

Our success depends in large part on our ability to obtain and maintain patent, trade secret and other intellectual property protection in the U.S. and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the U.S. and abroad related to our novel product candidates that are important to our business. The patent application and approval process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

If the scope of the patent protection we obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, contractors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the

scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the U.S. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than U.S. law does.

Some of our future patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we would need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our patents covering our proprietary technology maybe subject to challenge, narrowing, circumvention and invalidation by third parties.

Any of our patents may be challenged, narrowed, circumvented, or invalidated by third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may be subject to a third party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to our product candidates but that uses a technology that falls outside the scope of our patent protection. Our competitors may also seek approval to market generic versions of any approved products and in connection with seeking such approval may claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We cannot be sure that we were the first to make the technologies claimed in our patents or patent applications or that we were the first to file for patent protection.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the U.S., the first to

invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed patent applications on inventions claimed in our patents or applications on or before March 15, 2013, an interference proceeding in the U.S. can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the U.S. can be initiated by such third parties to determine whether our invention was derived from theirs.

The patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, narrowed, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the composition, use and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as

well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The ultimate determination by the USPTO or by a court or other trier of fact in the U.S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be insufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects

Obtaining and maintaining patent protection of our technologies depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Under the terms of some of our licenses, we do not have the ability to maintain or prosecute patents in the portfolio, and must therefore rely on third parties to comply with these requirements. Failure by us or our licensors to maintain protection of our patent portfolio could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, it is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our present or future partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S.legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U.S., including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms U.S. patent law in part by changing the U.S. patent system from a “first to invent” system to a “first inventor to file” system, expanding the definition of prior art, and developing a post-grant review system. This legislation changed U.S. patent law in a way that may weaken our ability to obtain patent protection in the U.S. for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the U.S., including post-grant review and *inter partes* review proceedings, which some third parties have

been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

In addition, recent court rulings in cases such as *Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation, Promega Corp. v. Life Technologies Corp. and Abbvie Deutschland GmbH v. Janssen Biotech, Inc.* have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any changes to patent law in the U.S. or other jurisdictions that impairs our ability to protect our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the U.S. and Europe do not afford intellectual property protection to the same extent as the laws of the U.S. and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the U.S. and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Agreements through which we license patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Others may claim an ownership interest in our intellectual property and proprietary technologies which could expose us to litigation and have a significant adverse effect on our prospects.

A third party may claim an ownership interest in one or more of our or our, or our licensors', patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third-parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates that may cover our product candidates or approach to complement inhibition. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, or our approach to complement inhibition, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that

we have identified each and every patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property and proprietary technology.

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the

ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate, or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any such litigation could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We may be reliant upon licenses to certain patent rights and proprietary technology form third parties that are important or necessary to the development of our product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Our licensors may have relied on third party consultants or collaborators or funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, the agreements under which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We cannot be certain that patent prosecution and maintenance activities by our

licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in any licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Further, the agreements under which we currently license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under current and any future collaborative development relationships;
- our diligence obligations under any license agreement and what activities satisfy such obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our license counterparties and us and our partners; and
- the priority of invention of patented technology.

In spite of our best efforts, our license counterparties might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, which may remove our ability to develop and commercialize the product candidates and technology covered by these license agreements. If any in-licenses are terminated, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. It is possible that we may be unable to obtain any additional licenses that we require at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates, technology, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed.

In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. However, trade secrets are difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and

the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

RISKS RELATED TO THIS OFFERING AND OWNERSHIP OF OUR COMMON STOCK

After this offering, our management will maintain the ability to substantially influence all matters submitted to stockholders for approval.

Upon completion of this offering, assuming the sale by us of all of the shares set forth on the cover page of this prospectus (other than shares subject to the underwriter's option to purchase additional shares), our management will, in the aggregate, beneficially own shares representing approximately % of our capital stock. As a result, they would be able to substantially influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons would substantially influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company that our public stockholders disagree with.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of , 2017, including shares of common stock to be issued upon automatic conversion of our preferred stock, all of which may be resold in the public market immediately without restriction, other than shares owned by our affiliates, which may be sold pursuant to Rule 144. However, the resale of an aggregate of shares will be restricted as a result of lock-up agreements executed in conjunction with this offering, as described in the "Shares Eligible for Future Sale" and "Underwriting" sections of this prospectus. We may register all shares of common stock that we may issue under our equity compensation plans on a Registration Statement on Form S-8. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Shares Eligible for Future Sale" section of this prospectus.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per share, representing the difference between the assumed public offering price and our as adjusted net tangible book value per share as of after giving effect to this offering. See "Dilution."

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If securities analysts do not commence coverage of us, the trading price of our stock could decrease. Additionally, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The offering price for the shares of our common stock sold in this offering will be determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. In addition, the market price of our common stock is likely to be highly volatile due to many factors, including:

- our ability to successfully proceed to and conduct clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;

- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

An active trading market for our common stock may not develop and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although we intend to apply to list our common stock on the Nasdaq Capital Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price of our common stock will be determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

We have broad discretion in the use of our cash, including the net proceeds from this offering, and may not use them effectively.

Our management will have broad discretion in the application of our cash, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See "Use of Proceeds."

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

We may seek additional capital through a combination of public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms unfavorable to us.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company: (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act; (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board; (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. Investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards.

We will incur increased costs as a result of operating as a smaller reporting public company, and our management will be required to devote substantial time to new compliance initiatives.

As a smaller reporting public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described in the preceding risk factor. We may remain an emerging growth company until the end of the fiscal year in which the fifth anniversary of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any September 30 before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of nonconvertible debt over a three-year period.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Provisions in our amended and restated corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We intend to amend and restate our corporate charter and bylaws upon the effectiveness of this Registration Statement. Provisions in our corporate charter, as amended, and our bylaws, as amended, may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our

board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 80% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains a number of "forward-looking statements." Specifically, all statements other than statements of historical facts included in this prospectus regarding our financial position, business strategy and plans and objectives of management for future operations are forward-looking statements. These forward-looking statements are based on the beliefs of management at the time these statements were made, as well as assumptions made by and information currently available to management. When used in this prospectus and the documents incorporated by reference herein, the words "anticipate," "believe," "estimate," "expect," "may," "will," "continue" and "intend," and words or phrases of similar import, as they relate to our financial position, business strategy and plans, or objectives of management, are intended to identify forward-looking statements. These statements reflect our current view with respect to future events and are subject to risks, uncertainties and assumptions related to various factors.

You should understand that the following important factors, in addition to those discussed in our periodic reports to be filed with the SEC under the Securities Exchange Act of 1934, as amended, or the Exchange Act, could affect our future results and could cause those results to differ materially from those expressed in such forward-looking statements:

- our clinical trials, including two Phase III clinical trials for MicroProst and MicroStat;
- our ability to implement our business plan to commercialize our product candidates, if they are approved;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for MicroProst, MicroStat, MicroTears, MicroPine and other product candidates;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash on hand and proceeds of this offering;
- the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expectations related to the use of proceeds from this offering;
- our ability to attract key personnel;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding;
- general or regional economic conditions;
- changes in U.S. GAAP or in the legal, regulatory and legislative environments in the markets in which we operate; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

Although we believe that our expectations (including those on which our forward-looking statements are based) are reasonable, we cannot assure you that those expectations will prove to be correct. Should any one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results may vary materially from those described in our forward-looking statements as anticipated, believed, estimated, expected or intended.

Except for our ongoing obligations to disclose material information under the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or any other reason. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus and the documents incorporated by reference herein might not occur.

INDUSTRY AND MARKET DATA

We obtained the industry, statistical and market data in this prospectus from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. In presenting this information, we have made assumptions based on such data and other similar sources, and on our knowledge of, and our experience to date in, the potential markets for our product candidates. Although we believe the data from these third-party sources is reliable, we have not independently verified any third-party information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $ million (or $ million if the underwriters exercise in full their option to purchase additional shares), assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 1.0 million increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by $ million, assuming the assumed initial public offering price per share remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

As of September 30, 2017, we had cash of approximately $7.4 million. We intend to use the net proceeds from this offering, together with our existing cash, as follows:

- Approximately $ to complete Phase III clinical trials for MicroProst;
- Approximately $ to complete Phase III clinical trials for MicroStat;
- Approximately $ to complete MicroTears registration activities;
- Approximately $ to complete scale-up engineering and manufacturing for pivotal trials and FDA approval;
- Approximately $ to complete formulation work for each development program; and
- Approximately $ for working capital and general corporate purposes.

We believe that our current cash, along with the net proceeds from this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements for the next 24 months.

The expected net proceeds of this offering will not be sufficient for us to fund commercialization of any of our product candidates (including marketing and sales) and we will need to raise substantial additional capital to complete the commercialization of our product candidates, as well as to establish an in-house manufacturing facility.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our preclinical and clinical trials and other development and commercialization efforts for our product candidates, as well as the amount of cash used in our operations. Although we have no present intention or commitment to do so, we may use a portion of the net proceeds for the acquisition of, or investment in, technologies, intellectual property or businesses that complement our business.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will retain broad discretion over the allocation of the net proceeds of this offering. Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2017:

- on an actual basis;
- on a pro forma basis to give effect to the reclassification of proceeds related to the sale of Series B preferred stock from liability to equity upon the subsequent ratification of such issuance by the Company and the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 17,400,772 shares of common stock, which conversion will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of common stock in this offering at an assumed public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding any additional shares of common stock that may be issuable upon the exercise of the underwriters' option to purchase additional shares.

The pro forma and pro forma as adjusted information set forth in the table below is illustrative only and will be adjusted based on the actual initial public offering price and other final terms of this offering. You should read this information together with our financial statements and the related notes thereto and the information set forth under the headings "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	As of September 30, 2017		
(in thousands, except share and per share amounts)	Actual	Pro Forma	Pro Forma As Adjusted[1]
		(unaudited)	
Non-Current Liabilities	$ 6,409,651	$	$
Stockholders' Equity:			
Preferred stock, $0.0001 par value, 30,000,000 shares authorized;			
Series A Convertible Preferred Stock, 20,000,000 shares designated, 10,996,614 shares issued and outstanding at September 30, 2017, no shares issued and outstanding pro forma or pro forma as adjusted (unaudited)	1,100		
Series A-2 Convertible Preferred Stock, 5,714,286 shares designated, 2,958,100 shares issued and outstanding at September 30, 2017, no shares issued and outstanding pro forma or pro forma as adjusted (unaudited)	296		
Series B Convertible Preferred Stock, 10,000,000 shares designated, 0 shares issued and outstanding at September 30, 2017, no shares issued and outstanding pro forma or pro forma as adjusted (unaudited)	0		
Common stock; $0.0001 par value; 60,000,000 shares September, 9,624,488 shares issued and outstanding at September 30, 2017, and shares issued and outstanding pro forma, and shares issued and outstanding pro forma as adjusted (unaudited)	962		
Additional paid-in capital	17,781,907		
Accumulated deficit	(17,098,755)		
Total Stockholders' Equity	685,510		
Total Capitalization	$ 685,510	$	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above excludes the following:

- 6,316,534 shares of our common stock underlying outstanding options to purchase common stock with a weighted average exercise price of $0.45; and
- 183,466 shares of our common stock reserved for future issuance under our 2014 Equity Incentive.

DILUTION

If you invest in our common stock, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value dilution per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after the completion of this offering.

As of September 30, 2017, our net tangible book value was approximately $0.7 million, or $0.07 per share of common stock. Net tangible book value per share represents the amount of our tangible assets less our liabilities divided by the total number of shares of our common stock outstanding as of September 30, 2017. Our pro forma net tangible book value as of September 30, 2017 was $ million, or $ per share, based on the total number of shares of our common stock outstanding as of September 30, 2017, after giving effect to the automatic conversion of all outstanding shares of our preferred stock as of September 30, 2017 into an aggregate of 17,400,772 shares of common stock, which conversion will occur immediately prior to the closing of this offering.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2017 would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	$
Historical net tangible book value per share as of September 30, 2017	
Pro forma decrease per share attributable to the pro forma transactions and other adjustments described above	
Pro forma net tangible book value per share as of September 30, 2017	
Increase in pro forma net tangible book value per share attributable to new investors in this offering	
Pro forma as adjusted net tangible book value per share immediately after this offering	
Dilution in pro forma net tangible book value per share to new investors in this offering	$

Each $1.00 increase (decrease) in the assumed initial public offering price of $, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution per share to new investors participating in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 1.0 million increase (decrease) in the number of shares offered by us would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution per share to new investors participating in this offering by $ per share, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase up to additional shares of common stock to cover over-allotments, if any, the pro forma as adjusted net tangible book value per share after giving effect to this offering would be $ per share, representing an immediate increase to existing stockholders of $ per share and immediate dilution to new investors participating in this offering of $ per share assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

To the extent any outstanding options to purchase common stock are exercised, new investors would experience further dilution.

The following table summarizes, on a pro forma basis as of September 30, 2017, the differences between the number of shares of common stock purchased from us, the total cash consideration and the average price per share paid to us by existing stockholders and by new investors purchasing shares in this offering, at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New public investors					$
Total		100%	$	100%	

If the underwriters exercise their option to purchase additional shares in full, the number of shares of common stock held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to % of the total number of shares of common stock to be outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering excludes:

- 6,316,534 shares of our common stock underlying outstanding options to purchase common stock with a weighted average exercise price of $0.45; and
- 183,466 shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan.

SELECTED FINANCIAL DATA

The selected statements of operation data for the years ended December 31, 2016 and December 31, 2015 and the balance sheet data as of December 31, 2016 and December 31, 2015 have been derived from our audited financial statements appearing elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2017 and September 30, 2016 and the balance sheet data as of September 30, 2017 have been derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of our management, contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair statement of such financial data. You should read this data together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information under the captions "Risk Factors," "Capitalization," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and our operating results for the nine months ending September 30, 2017 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2017 or any other interim periods or any future year or period.

	Nine Months Ended September 30,		Year Ended, December 31,	
	2017	2016	2016	2015
	(unaudited)			
Statement of Operations Data:				
Operating Expenses:				
Research and development	$ 2,125,993	$ 1,985,536	$ 2,966,165	$ 2,783,200
General and administrative	842,959	391,945	568,775	1,486,401
Total Operating Expenses	2,968,952	2,377,481	3,534,940	4,269,601
Loss from Operations	(2,968,952)	(2,377,481)	(3,534,940)	(4,269,601)
Other Income:				
Interest income	1,396	921	1,497	2,412
Total Other Income	1,396	921	1,497	2,412
Net Loss	$(2,967,556)	$(2,376,560)	$(3,533,443)	$(4,267,189)
Net Loss Per Share–Basic and Diluted	$ (0.35)	$ (0.28)	$ (0.42)	$ (0.50)
Weighted Average Number of Common Shares Outstanding–Basic and Diluted				
Diluted	8,514,906	8,500,000	8,500,000	8,500,000

	As of September 30, 2017	As of December 31,	
		2016	2015
	(unaudited)		
Balance Sheet Data:			
Cash	$ 7,406,034	$3,387,288	$2,492,611
Working capital	$ 6,946,806	$2,965,889	$2,385,621
Total assets	$ 7,689,230	$3,432,815	$2,818,319
Total liabilities	$ 7,003,720	$ 423,734	$ 419,823
Total stockholders' equity	$ 685,510	$3,009,081	$2,398,496

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

The following discussion and analysis is based on, and should be read in conjunction with our financial statements, which are included elsewhere in this prospectus. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this prospectus, and other factors that we may not know.

Overview

We are a clinical stage biopharmaceutical company developing a pipeline of ophthalmology products utilizing our patented piezo-print technology to deliver micro-doses (6–8 µL) of active pharmaceutical ingredients, or micro-therapeutics, topically to the eye. This micro-dosing technology has the potential to replace traditional macro-dosing applications (e.g. conventional eye droppers) that routinely overdose or under-dose when used in the topical administration of ophthalmic therapeutics. We believe our micro-therapeutic product candidates may be able to achieve similar pharmacologic effects as traditional macro-dosing applications while reducing the adverse effects associated with these techniques. We have received written FDA feedback indicating that we can proceed to Phase III clinical trials for two of our lead programs: MicroProst, a novel micro-therapeutic latanoprost formulation for CACG, an indication with no FDA-approved drug treatments; and MicroStat, a fixed combination of micro-therapeutic phenylephrine-tropicamide formulation for mydriasis, also known as pupil dilation for use in eye exams. MicroTears, our OTC product candidate for dry eye, will not require Phase III clinical trials, and we plan to proceed with registration activities.

We have completed two Phase II clinical trials, treating more than 110 subjects, with results published in peer-reviewed literature. Applying multiple front-of-the-eye (the area in front of the lens) formulations in subjects for mydriasis, our piezo-print technology delivered microliter precision at the volume of the eye's natural tear film capacity of 6–8 µL, which reduced ocular and systemic drug and preservative exposure when compared to eye drops, resulting in comparable efficacy with fewer side effects. We believe that these clinical trials support our advancement into late stage clinical trials utilizing the 505(b)(2) pathway. We intend to use this pathway for future clinical trials in new indications with significant unmet needs. We plan to commence clinical trials for MicroProst and MicroStat in the second half of 2018, pending IND submission and FDA feedback.

We have not completed development of any product candidate and we have therefore not generated any revenues from product sales.

Historically, we have financed our operations principally through private placements of preferred stock. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, and assuming the successful closing of this offering of common stock, we believe we will have sufficient cash to meet our projected operating requirements for the next 24 months. If we do not raise an aggregate of $30 million or more from this offering, the proceeds would be insufficient to complete planned development and clinical trials for MicroStat, MicroTears and MicroProst.

Our net losses were $3.5 million and $4.3 million for the years ended December 31, 2016 and 2015, respectively. Our net losses were $3.0 million and $2.4 million for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we had an accumulated deficit of $17.1 million.

Financial Overview

Revenue

We have not generated any revenue from product sales since our inception and do not expect to generate any revenue from the sale of products in the near future. Our ability to generate revenues will depend heavily on the successful development, regulatory approval and commercialization of our micro-therapeutic product candidates.

Research and Development Expenses

Research and development expenses are incurred in connection with the research and development of our micro-therapeutics and consist primarily of contract service expenses. Our research and development expenses consist of:

- direct clinical and non-clinical expenses which include expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations and costs associated with preclinical activities and development activities and costs associated with regulatory activities;
- consultant-related expenses, including consulting compensation and travel for research and development consultants that conduct and support clinical trials and preclinical studies; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in research and development activities.

We expense research and development costs as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or other information our vendors provide to us.

We expect that our research and development expenses will increase with the continuation of the aforementioned initiatives.

General and Administrative Expenses

General and administrative expenses consist primarily of legal and other professional services, as well as non-cash stock-based compensation expense. We anticipate that our general and administrative expenses will increase during the remainder of 2017 and in the future as we increase our headcount to support our continued research and development and the potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with being a public company.

Results of Operations

Nine Months Ended September 30, 2017 Compared with Nine Months Ended September 30, 2016

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2017 totaled $2.1 million, an increase of approximately $0.1 million, or 7%, as compared to $2.0 million recorded for the nine months ended September 30, 2016.

General and Administrative Expenses

General and administrative expense for the nine months ended September 30, 2017 totaled $0.8 million, an increase of $0.4 million, or 115%, as compared to the $0.4 million recorded for the nine months ended September 30, 2016. The increase was primarily attributable to increased non-cash stock-based compensation costs, expenses related to supplies and materials, and payroll expenses as compared to 2016.

Year Ended December 31, 2016 Compared with Year Ended December 31, 2015

Research and Development Expenses

Research and development expenses for the year ended December 31, 2016 totaled $3.0 million, an increase of approximately $0.2 million, or 7%, as compared to the $2.8 million recorded for the year ended December 31, 2015.

General and Administrative Expenses

General and administrative expense for the year ended December 31, 2016 totaled $0.6 million, a decrease of $0.9 million, or 62%, as compared to the $1.5 million recorded for the year ended December 31, 2015. The decrease was primarily attributable to reduced non-cash stock-based compensation costs as compared to 2015.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of preferred stock. At September 30, 2017, our accumulated deficit since inception was approximately $17.1 million.

At September 30, 2017, we had total current assets of approximately $7.5 million and current liabilities of approximately $0.6 million, resulting in working capital of approximately $6.9 million. At September 30, 2017, we had total assets of approximately $7.7 million and total liabilities of approximately $7.0 million, resulting in stockholders' equity of $0.7 million.

At September 30, 2017, December 31, 2016 and December 31, 2015, we had no debt outstanding.

At September 30, 2017, we had a cash and cash equivalents balance of approximately $7.4 million. We expect our current cash on hand to be sufficient to meet our operating and capital requirements for at least the next twelve months from the date of this filing. Thereafter, we will need to raise further capital, through the sale of additional equity or debt securities, to support our future operations. Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings.

We believe that our current cash, along with the net proceeds from this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements for the next 24 months.

During the nine months ended September 30, 2017 and 2016 and the years ended December 31, 2016 and 2015, our sources and uses of cash were as follows:

Net cash used in operating activities for the year ended December 31, 2016 was approximately $3.2 million, which includes cash used to fund a net loss of approximately $3.5 million, partially offset by approximately $0.3 million of cash provided by changes in operating assets and liabilities. Net cash used in operating activities for the year ended December 31, 2015 was approximately $3.8 million, which includes cash used to fund a net loss of approximately $4.3 million, reduced by non-cash charges of approximately $0.9 million, plus approximately $0.5 million of cash used to fund changes in operating assets and liabilities. Net cash used in operating activities for the nine months ended September 30, 2017 was approximately $2.7 million, which includes cash primarily used from a net loss of approximately $3.0 million, reduced by non-cash charges of approximately $0.2 million. Net cash used in operating activities for the nine months ended September 30, 2016 was approximately $2.3 million, which was primarily attributable to cash used to fund a net loss of approximately $2.4 million, partially offset by $0.1 million of cash provided by changes in operating assets and liabilities.

Net cash used in investing activities was less than $0.1 million for all periods presented and was attributable to purchases of property and equipment.

Cash provided by financing activities for the year ended December 31, 2016 totaled approximately $4.1 million, which related to the sale of Series A-2 convertible preferred stock. Cash provided by financing activities for the year ended December 31, 2015 totaled approximately $5.0 million, which related to the sale of Series A convertible preferred stock. Cash provided from financing activities for the nine months ended September 30, 2017 totaled approximately $6.8 million, which primarily related to advances related to the sale of Series B convertible preferred stock. Cash provided from financing activities for the nine months ended September 30, 2016 totaled approximately $4.1 million, which related to the sale of Series A-2 convertible preferred stock.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements between the Company and any other entity that have, or are reasonably likely to have, a current or future effect on financial conditions, changes in financial conditions, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Policies

Use of Estimates

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and the amounts disclosed in the related notes to the financial statements. We base our estimates and judgments on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The amounts of assets and liabilities reported in our balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, fair value calculations for equity securities, establishing valuation allowances for deferred taxes, stock-based compensation, the recoverability and useful lives of long-lived assets and the recovery of deferred costs. Certain of our estimates could be affected by external conditions, including those unique to us and general economic conditions. It is reasonably possible that these external factors could have an effect on our estimates and could cause actual results to differ from those estimates.

Convertible Instruments

We evaluate our convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Topic 815 of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). The accounting treatment of derivative financial instruments requires that we record embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. We reassess the classification of our derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Embedded conversion options and any related freestanding instruments are recorded as a discount to the host instrument.

If the instrument is determined to be a derivative liability, we then evaluate for the existence of a beneficial conversion feature by comparing the market price of our common stock as of the commitment date to the effective conversion price of the instrument.

Preferred Stock

We apply the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of our preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within our control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

We utilize a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in our financial statements as of December 31, 2016 and 2015 and September 30, 2017 and 2016. We do not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

Our policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the statements of operations.

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. The fair value of our equity instruments was estimated by management based on observations of the cash sales prices of our convertible preferred stock. Awards granted to directors are treated on the same basis as awards granted to employees. Upon the exercise of an option, we issue new shares of common stock out of our authorized shares.

Research and Development

Research and development expenses are charged to operations as incurred.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers," ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC 605 — Revenue Recognition ("ASC 605") and most industry-specific guidance throughout ASC 605. The standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The guidance in ASU 2014-09 was revised in July 2015 to be effective for interim periods beginning on or after December 15, 2017 and should be applied on a transitional basis either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. In 2016, FASB issued additional ASUs that clarify the implementation guidance on principal versus agent considerations (ASU 2016-08), on identifying performance obligations and licensing (ASU 2016-10), and on narrow-scope improvements and practical expedients (ASU 2016-12) as well as on the revenue recognition criteria and other technical corrections (ASU 2016-20). Since we have not generated any revenue since our inception, we do not anticipate that the adoption of these ASUs will have a material impact on our financial position, results of operations, and cash flows.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," ("ASU 2014-15"). ASU 2014-15 explicitly requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist which raise substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and annual and interim periods thereafter, with early adoption permitted. We adopted this standard effective January 1, 2015 and its adoption did not have a material impact on our financial position, results of operations, and cash flows.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes," ("ASU 2015-17"). The FASB issued ASU 2015-17 as part of its ongoing Simplification Initiative, with the objective of reducing complexity in accounting standards. The amendments in ASU 2015-17 require entities that present a classified balance sheet to classify all deferred tax liabilities and assets as a noncurrent amount. This guidance does not change the offsetting requirements

for deferred tax liabilities and assets, which results in the presentation of one amount on the balance sheet. Additionally, the amendments in ASU 2015-17 align the deferred income tax presentation with the requirements in International Accounting Standards (IAS) 1, Presentation of Financial Statements. The amendments in ASU 2015-17 are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We do not anticipate that the adoption of this standard will have a material impact on our financial position, results of operations, and cash flows.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," ("ASU 2016-02"). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. We are currently evaluating ASU 2016-02 and its impact on our financial position, results of operations, and cash flows.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation — Stock Compensation (Topic 718)," ("ASU 2016-09"). ASU 2016-09 requires an entity to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, with early adoption permitted. We are currently evaluating ASU 2016-09 and its impact on our financial position, results of operations, and cash flows.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments," ("ASU 2016-15"). The new standard will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017. We will require adoption on a retrospective basis unless it is impracticable to apply, in which case we would be required to apply the amendments prospectively as of the earliest date practicable. We are currently evaluating ASU 2016-15 and its impact on our financial position, results of operations, and cash flows.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting," ("ASU 2017-09"). ASU 2017-09 provides clarity on the accounting for modifications of stock-based awards. ASU 2017-09 requires adoption on a prospective basis in the annual and interim periods for our fiscal year ending December 15, 2017 for share-based payment awards modified on or after the adoption date. We are currently evaluating ASU 2017-09 and its impact on our financial position, results of operations, and cash flows.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260) and Derivatives and Hedging (Topic 815) — Accounting for Certain Financial Instruments with Down Round Features," ("ASU 2017-11"). Equity-linked instruments, such as warrants and convertible instruments may contain down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. Under ASU 2017-11, a down round feature will no longer require a freestanding equity-linked instrument (or embedded conversion option) to be classified as a liability that is remeasured at fair value through the income statement (i.e. marked-to-market). However, other features of the equity-linked instrument (or embedded conversion option) must still be evaluated to determine whether liability or equity classification is appropriate. Equity classified instruments are not marked-to-market. For earnings per share ("EPS") reporting, the ASU requires companies to recognize the effect of the down round feature only when it is triggered by treating it as a dividend and as a reduction of income available to common shareholders in basic EPS. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in any interim period. We are currently evaluating ASU 2017-11 and its impact on our financial position, results of operations, and cash flows.

BUSINESS

Overview

We are a clinical stage biopharmaceutical company developing a pipeline of ophthalmology products utilizing our patented piezo-print technology to deliver micro-therapeutics topically to the eye. This micro-dosing technology has the potential to replace traditional macro-dosing applications (e.g. conventional eye droppers that deliver 30–50 µL) that routinely overdose or under-dose when used in the topical administration of ophthalmic therapeutics. We believe our micro-therapeutic product candidates may be able to achieve similar pharmacologic effects as traditional macro-dosing applications while reducing the adverse effects associated with these techniques. We have received written FDA feedback for our Phase III clinical trials for two of our lead programs: MicroProst, a novel micro-therapeutic latanoprost formulation for CACG, an indication with no FDA-approved drug treatments; and MicroStat, a fixed combination of micro-therapeutic phenylephrine-tropicamide formulation for mydriasis, also known as pupil dilation for use in eye exams. MicroTears, our OTC product candidate for dry eye, will not require Phase III clinical trials, and we plan to proceed with registration activities.

All of our product candidates utilize our patented piezo-print micro-dosing technology to enable the topical delivery of ophthalmic micro-therapeutics. Micro-dosing has long been the goal for ophthalmic medications because the eye only holds 6–8 µL, yet traditional eye drops overdose the eye with 30–50 µL, which frequently leads to adverse side effects such as redness, irritation and pain, increased risk of certain cardiac and respiratory side effects, as well as inconveniences such as overflow down the cheek and into the nose through the naso-lacrimal duct or under-dosing in patients that lack motor control to properly use a conventional eyedropper and thus administer the drops outside the eye. We believe our easy-to-use piezo-print technology may enable patients to consistently deliver doses of 6–8 µL of ocular therapeutics, representing maximum eye capacity, and reduce ocular exposure to preservatives and pharmaceutical ingredients by over 75%.

We have completed two Phase II clinical trials, treating more than 110 subjects, with results published in peer-reviewed literature. Applying multiple front-of-the-eye (the area in front of the lens) formulations in subjects for mydriasis, our piezo-print technology delivered microliter precision at the volume of the eye's natural tear film capacity of 6–8 µL, which reduced ocular and systemic drug and preservative exposure when compared to eye drops, resulting in comparable efficacy and fewer side effects. We believe that these clinical trials support our advancement into late stage clinical trials through the 505(b)(2) pathway. We intend to use this pathway for future clinical trials in new indications with significant unmet needs.

A key feature of our patented technology is the embedded electronic, smartphone enabled "e-health" system which we believe is the first ever intelligent electronic delivery system for ophthalmic therapies. Our electronic functions are designed to enable patients and physicians to track when doses are administered to better monitor and improve patient compliance.

The following summarizes our product pipeline and expected milestones:

Product Candidate	Indication	Next Expected Milestones
MicroProst	Chronic Angle Closure Glaucoma	Phase III IND H2 2018
MicroStat	Mydriasis (Pupil Dilation)	Phase III IND H2 2018
MicroTears	Dry Eye	OTC Registration H1 2019
MicroPine	Myopia (Near Sightedness)	Phase III IND H1 2019

In addition to MicroProst, MicroStat and MicroTears, we are developing an expanded pipeline of product candidates and are preparing them for late-stage clinical trials. The first pipeline opportunity is MicroPine, which is a micro-therapeutic formulation of atropine to target myopia (or near sightedness) progression. Clinical trials conducted to date, as well as a recent technology analysis and review by the American Academy of Ophthalmology, indicate Level 1 (highest) evidence of efficacy for the role of low dose atropine for myopia progression. To date, no therapy has been possible due to side effects associated with existing macro-dosed drop formulations in the pediatric population using atropine. We have begun development activities for MicroPine with a planned Phase III clinical trial expected to be initiated in 2019.

Our management team is a critical component to the execution of our overall strategy and our business model. We have assembled a team with significant experience in translational science, drug evaluation, clinical development, regulatory affairs and business development. Our management team is led by our Chief Executive Officer, Dr. Tsontcho Ianchulev, who has over 15 years of experience in public health, life-science and medical technology covering the spectrum of biotech and med-tech. He is a prolific inventor, innovator, physician-executive and public health expert who has been at the core of developing medical products and technologies which have transformed the ophthalmic field and are impacting medical care for hundreds of thousands of patients every year. His intellectual property was a core asset to WaveTec's (acquired by Alcon) technology for intraoperative aberrometry. While at Genentech, Inc., Dr. Ianchulev headed the ophthalmology research group and directed the development and the FDA approval of Lucentis, the most successful specialty biologic in the field of ophthalmology with more than $4 billion of annual sales in 2015. Most recently, he headed all clinical development of Transcend Medical's (acquired by Alcon) micro-stent for glaucoma. Dr. Ianchulev's clinical experience, combined with development and commercial work in both biopharmaceuticals and medical devices make him ideally suited to lead Eyenovia.

In addition to Dr. Ianchulev, the management team has other professionals with deep engineering, clinical trial, regulatory and commercial experience in ophthalmology. Our management team is supported by our Board of Directors, which has extensive professional experience in strategic development, executive, operational and financial leadership in the pharmaceutical and healthcare industries, including several successful ophthalmology companies.

Strategy

Our goal is to become a leading biopharmaceutical company focused on developing and commercializing novel therapies for front-of-the-eye conditions by utilizing our micro-therapeutic piezo-print technology. The key elements of our strategy to achieve this goal are:

Establish a portfolio of first-in-class piezo-print micro-therapeutic products for front-of-the-eye treatments through the 505(b)(2) pathway with the FDA. We are initially focused on developing technology utilizing therapeutic compounds already well established in the topical treatment of ophthalmic indications. We believe the 505(b)(2) registration pathway, which reduces development risk compared to new molecular entity programs, will be available for our initial development pipeline. We believe our pipeline of patented micro-therapeutic product candidates will be highly differentiated by our improved tolerability and enhanced compliance profile and our late-stage development programs could lead to NDA submissions in novel indications where the products can have unique dosing and therapeutic profiles. We believe that this could lead to favorable pricing and reimbursement, and a reduced risk of generic substitution.

Improve clinical outcomes and patient experiences while providing an improved tolerability profile with our micro-therapeutics. We believe our piezo-print platform will allow for high precision targeted micro-dosing for front-of-the-eye treatments, while eliminating ophthalmic over-dosing and reducing ocular exposure to toxic preservatives and pharmacologic ingredients by over 75% compared to conventional eye drop delivery mechanisms. Our clinical trials have demonstrated equivalent biologic activity, improved side effect profile and enhanced patient experience of our micro-therapeutic approach as compared to conventional eye drops.

Leverage our electronic, smartphone-enabled "e-health" technology to introduce and develop patient-specific compliance monitoring program. Our mobile e-health technology and smart cartridges are designed to track when a patient administers treatments, allowing physicians to track patient compliance accurately. We believe this may enhance patient compliance and improve compliance monitoring by empowering patients and physicians with access to dynamic, real-time monitoring and compliance data for a more intelligent, informed and personalized therapeutic paradigm.

Develop micro-therapeutic treatments for other ophthalmic diseases independently or in collaboration with third parties. Our piezo-print technology is also suitable for new molecular entities. Leveraging our existing platform technology, we plan to continue developing other micro-therapeutic product candidates for front-of-the-eye diseases that can be administered using our piezo-print technology platform with

mobile e-health technology and smart cartridges either independently or through strategic partnerships with third parties. We have entered into an exclusive agreement with Senju Pharmaceuticals, a leading ophthalmology company in Japan, for the Asian development and commercial rights of our therapies and technology.

Develop solutions for ophthalmic conditions with high unmet needs and no approved therapy. We will target chronic ophthalmic conditions with a high unmet medical need. By leveraging our piezo-print micro-dosing technology, we aim to reach conditions where there are no approved therapies. For example, our MicroPine program which is a micro-formulation of atropine, is intended to slow myopia progression in the pediatric population. However, there are currently no therapies on the market due to side effects associated with traditional macro-dosing drop formulations.

Limitations of Conventional Front-of the-Eye Therapies

Our micro-dosing platform technology aims to address the following issues associated with eye drop-based therapies.

Dosing, administration and waste of medication

Multiple third party studies have confirmed the challenges with administering conventional eye drops including overdosing, poor compliance, imprecise dosing, variability in drop size, and patient difficulty in self-administering. One study in patients experienced in using eye drops undergoing treatment for glaucoma for at least 6 months documented that 9 out of 10 patients were unable to deliver topical treatment correctly at the end of the 6 month treatment. Patients on average administered almost twice the macro-dose with a range of one to eight drops (1.8+/-1.2), and 75% of patients risked bottle contamination or potential ocular trauma by having the eye dropper container touch their eyes. Another larger study in 139 patients demonstrated that the proportion of patients who were able to correctly deliver therapy on the eye was only 22%–30%. Other studies have demonstrated similarly that the vast majority of patients either overdose or do not administer correctly the required therapeutic to the eye, which leads to unnecessary waste of medication, a problem which is highlighted by recently introduced legislation in the U.S. Senate to address this specific concern.

Side effects associated with conventional macro-dose therapies

Conventional front-of-the-eye therapies are administered using 100-year-old eye-dropper pipette approaches. Current eye drop therapies consistently overdose the eye with 30–50 µL of preservatives and pharmaceutical ingredients while the eye only holds 6–8 µL. Thus, traditional drops severely overdose the eye, which is associated with many ocular side effects including hyperemia, or increased blood flow to the eye, redness, discomfort, stinging, blurred vision, burning, itching, excessive tearing, eye pain, iris pigment changes, foreign body sensation, pigment discoloration, periorbital dermatitis and sunken eye. For some topical medications, there are also major cardiovascular side effects such as bradycardia and arrhythmia that are caused when medications are absorbed into the circulation system from overdosing — both through conjunctiva absorption and when drugs flow into the nose through the naso-lacrimal duct and are absorbed in the nose or swallowed. For example, phenylephrine can cause cardiovascular adverse reactions including an increase in blood pressure, syncope, myocardial infarction, tachycardia, arrhythmia and subarachnoid hemorrhage. Severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported following systemic or ophthalmic administration of timolol maleate.

Prostaglandins are a widely-used class of drugs for glaucoma. However, as shown in the chart below, they present a high risk of ocular irritation and adverse events. We believe micro-dosing will result in fewer adverse events due to less exposure to the drug and preservatives.

Frequencies of Adverse Events (Safety Population)

	Latanoprost (n = 136)			Bimatoprost (n = 137)			Travoprost (n = 138)			
	n	%	No. of Events	n	%	No. of Events	n	%	No. of Events	*P* Value
Patients with at least one adverse event	87	64.0	137	104	75.9	200	95	68.8	159	.098
Patients with ocular adverse events	73	53.7	110	101	73.7	162	89	64.5	129	.003
Patients with systemic adverse events	23	16.9	27	25	18.2	38	23	16.7	30	.933
Patients with adverse events related to study medications	70	51.5	90	94	68.6	140	81	58.7	108	.015

Potential for toxicity

Many eye medications contain preservatives (e.g. benzalkonium chloride or BAC) which are toxic to the ocular surface. Cytotoxic assays have confirmed this and showed significant toxicity proportional to the concentration of BAC and its effects in causing ocular surface disease.

Another emerging problem with the prostaglandin-class of medications (e.g. latanoprost, bimatoprost, travoprost) has been the dose-related incidence of orbitopathy (or sunken orbits). The associations between prostaglandin analogue use and deepening of the upper lid sulci and between prostaglandin analogue use and loss of inferior periorbital fat were recently confirmed with a 230-fold increased risk of skin tissue shrinking around the eye.

Our Solution

We believe that we are the only company with clinical stage technology for targeted micro-dosing of ophthalmic investigational therapies. Our solution is based on piezo-print technology, which is also used for pixel-sharp high-precision ink jet printing. It is miniaturized, optimized for and applied in ophthalmic delivery to achieve micro-dosing that is many times more precise than conventional eye droppers. Our targeted micro-dosing delivers doses of 6–8 µL in a targeted way, directly coating the corneal surface rather than the conjunctiva thus reducing collateral tissue exposure and focusing on the cornea where 80% of intraocular drug penetration occurs. We believe micro-therapeutic product candidates reduce greater than 75% of the drug exposure to reduce toxicity, resulting in potentially gentler and more tolerable treatments. Our micro-therapeutic approach also reduces waste associated with conventional macro-dose drops — a problem that has been highlighted by recently introduced legislation in the U.S. Senate to address this specific concern.

In the ophthalmology space, we believe that our micro-therapeutics will come with first-in-class smart sensing technology for mobile e-health applications and compliance monitoring, which will be standard with all of our smart cartridges. This technology has the potential to improve compliance and chronic disease management by tracking each time a patient administers treatment, empowering patients and physicians with access to dynamic, real time monitoring and compliance data for a more intelligent and personalized therapeutic paradigm.

Our micro-therapeutic solution has been tested in preclinical models and clinical trials and has been shown to provide many advantages over the current administrations.

CONVENTIONAL EYE DROPPER USING CENTURY-OLD PIPETTE DELIVERY

× Overdoses the eye by more than 400%
× Causes overdose-related ocular toxicity (drug / preservative / excipient exposure)
- Hyperemia / red eye
- Discomfort / stinging
- Itching

× 50–80% of eye drop applications miss the eye

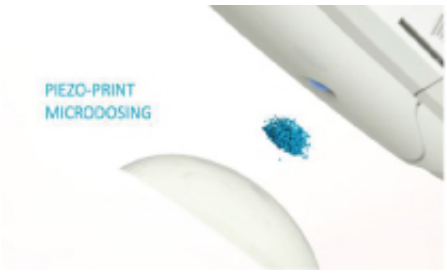
EYENOVIA'S HIGH-PRECISION PIEZO-PRINT MICRODOSING

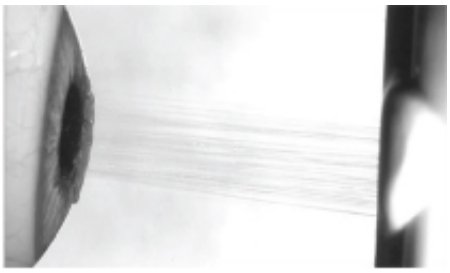
✓ Medication delivered directly to the cornea (primary site of ocular drug absorption)
✓ Gentle ocular surface microdroplet coating
✓ Less toxicity and drug/preservative exposure
✓ Fewer ocular side effects (redness, stinging)
✓ Lower systemic exposure

Key advantages of our micro-therapeutic platform include:

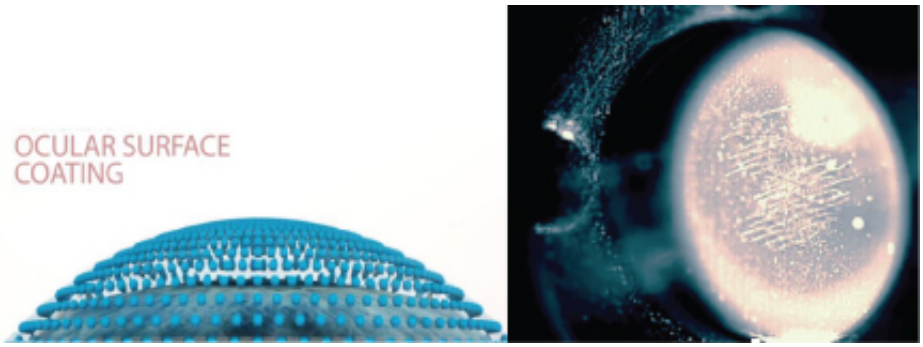
Dose reduction: Our micro-droplet delivery technology achieves precise volumetric control at the microliter level to deliver 6–8 µL, which is the physiologic capacity of the tear film compared to the dropper pipette macro-dose of 30–50 µL which results in overdosing, ocular toxicity and systemic leaching into the plasma.

Targeted dose instillation: Our piezo-print technology allows for targeted delivery to the ocular surface and cornea, avoiding the conjunctival cul-de-sac. The micro-jet created by the piezo-electric vibrations is columnated and focused to provide accurate delivery to the corneal surface where the majority of ocular penetration occurs. Additionally, our technology includes an LED targeting mechanism to allow proper positioning and objective alignment.





Speed of delivery: Similar to high-precision ink-jet printing that can deliver pixel-sharp ink printing, we use piezo-electric dispensation. Unlike a simple aerosolized mechanism, our patented piezo-printing technology achieves micro-droplet ejection control that creates a fast and targeted micro-jet delivery. We can deliver our micro-therapeutics to the ocular surface in less than 80 milliseconds beating the eye's 100 millisecond blink reflex.

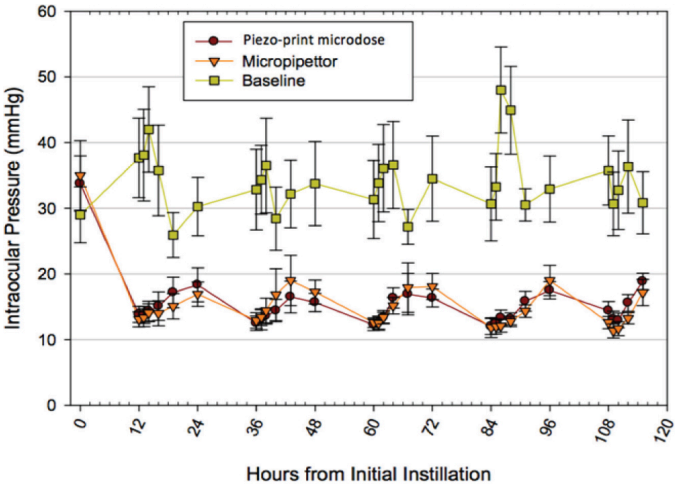


Smart electronics: Our smart electronics and mobile e-health technology are designed to track when a patient administers treatment. This enables physicians to monitor patient compliance accurately. We believe this technology will improve compliance and chronic disease management by empowering patients and physicians with access to dynamic, real time monitoring and compliance data for a more intelligent and personalized therapeutic paradigm.

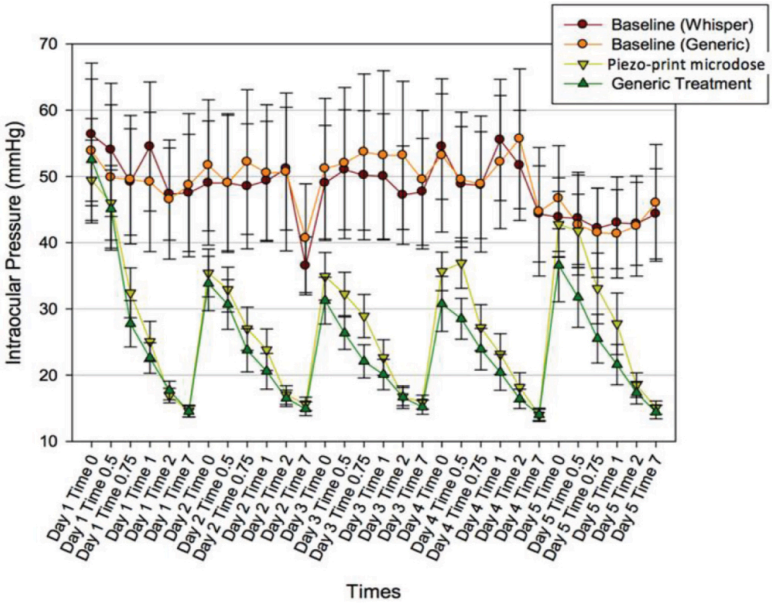
Clinical Trial Results

We have a proven platform for the delivery of micro-therapeutics. Our preclinical and clinical studies suggest that a micro-therapeutic dose of medication delivers clinical activity comparable to that of a macro-dose delivery via traditional eye drops, but with the advantages of fewer ocular side effects and less systemic exposure. We can use our platform technology on either new molecular entities, to increase their chances of approval, or with existing molecular entities in order to improve their safety. We have chosen the latter path for our initial pipeline product candidate.

To date, we have conducted multiple preclinical studies and two Phase II clinical trials to validate our piezo-print micro-dose delivery platform. Our micro-dose approach was studied in preclinical studies to demonstrate pharmacodynamic equivalence of our targeted micro-therapeutic formulations and to assess whether micro-dosing can achieve comparable biologic activity with its significantly lower levels of drug and preservative exposure to the ocular tissues. Data from a canine model of glaucoma demonstrated more than 40% IOP lowering effect at micro-dose of 8–9 µL latanoprost. Another independent micro-dose study published in the Journal of Investigative Ophthalmology and Visual Science in 2014 further demonstrated that 3 µL micro-dose with timolol 0.5% can reduce systemic plasma levels of the drug by a factor of 17.



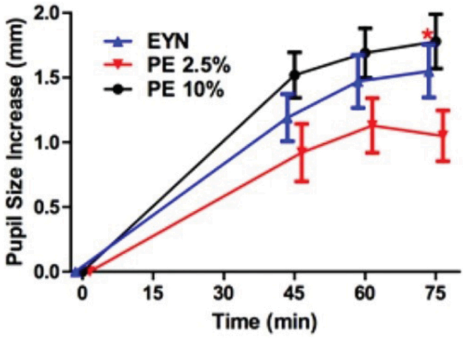
IOP Lowering Effect of Micro-Therapeutic Dose of Latanoprost in Canine Model



We have completed two Phase II clinical trials to investigate the pharmacodynamic equivalence and clinical advantages of our micro-therapeutic approach. In these studies, we examined whether a micro-therapeutic dose of phenylephrine would dilate the eye as compared to a macro-dose with a traditional eye drop, as well as the side effect incidence of micro-dosing vs. drops. Results of the two Phase II micro-dose clinical trials suggest that our micro-dose piezo-print technology can deliver equivalent therapeutic activity as conventional eye drop macro-dosing while reducing the incidence of side effects by reducing by greater than 75% the patient's exposure to preservatives and active pharmaceutical ingredients, which are the root cause of ocular surface toxicity, and topical and systemic adverse events associated with topical therapy.

The first clinical trial, which we refer to as the EYE102 Phase II clinical trial compared the mydriatic pharmacodynamic effect of our micro-dose (7 µL) Phenylephrine 10% versus standard dropper, which delivered 32 µL 10% phenylephrine (4 times our micro-dose of phenylephrine), versus an eye dropper that delivered 32 µL of phenylephrine 2.5% (same net amount of phenylephrine as our micro-dose). At 75 minute peak dilation, our micro-dose provided similar mydriatic activity at one quarter of the dose exposure of the dropper with 10% phenylephrine, and superior activity versus the equal dose exposure via 2.5% phenylephrine drops.

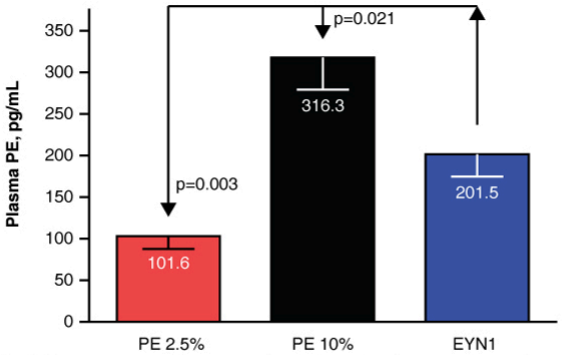
PUPIL DIAMETER, INCREASE FROM BASELINE, MM



Pupil diameter increase from baseline, at 45, 60, and 75 minutes post-administration of PE 2.5%, PE 10%, and EYN- each respectively administered on study Days 1, 7, and 14. Shown are mean±SEM for N=24 eyes of 12 subjects. Colored asterisk at t=75 min indicates significant difference versus comparator of asterisk color, in this case EYN vs PE 2.5% (p=0.009).

The study was also informative with regard to systemic drug exposure of topical treatment whereby the micro-dose product candidate demonstrated 35–40% lower plasma levels of the drug compared to same concentration macro-dose. There were also significantly fewer ocular adverse events, over macro-dosing.

PLASMA PE LEVELS AT 20 MINUTES



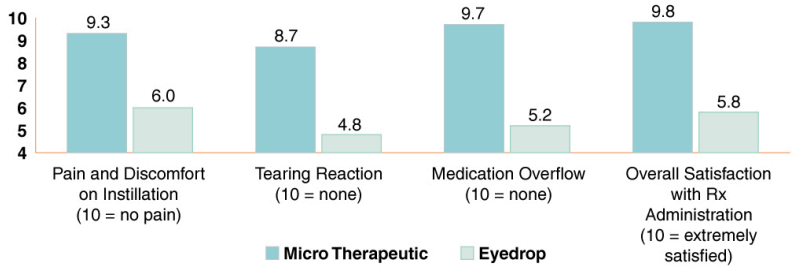
Plasma free PE concentration in venous blood drawn 20 minutes after ocular topical drug administration. Circulating PE was highest in PE 10% subjects (316.3±36.8 pg/mL), and was significantly 36.3% lower in EYN subjects (201.5±27.1 pg/mL; p=.021). Plasma PE was significantly lower in PE 2.5% subjects (101.2±12.9 pg/mL) than in EYN subjects (p=.003).

In the EYE102 Phase II clinical trial, the same formulation micro-dose also suggested significant improvement in tolerability as compared to conventional eye drops.

OCULAR ADVERSE EVENTS BY TREATMENT

Adverse Event Description	Eye Drop 10%	EYE102 (Micro-dose 10%)
Ocular blurriness	1	0
Ocular burning/stinging/irritation	4	1
Ocular dryness	2	0
Subtotal by Treatment Group	*7*	*1*

The other Phase II clinical trial in 102 subjects investigated micro-therapeutics treatment with combination of phenylephrine and tropicamide, the results of which were published in the peer-review journal Therapeutic Delivery. In the study, 91% of participants preferred micro-dose versus the eyedropper; 6% preferred the eye dropper and 3% expressed no preference ($p < 0.0001$). General satisfaction scores were higher with the micro-dose versus eyedropper (9.8 ± 0.6 vs 5.8 ± 3.0). Regarding ocular discomfort, our micro-dose was nearly two times better than the eyedropper.



At the end of our Phase II clinical trial, we had a meeting with the FDA and have received guidance on the design and requirements for Phase III development programs for MicroProst in CACG and MicroStat in mydriasis as well as the requirements for MicroTears for OTC dry eye. Based on this guidance, we expect to initiate pivotal programs in the second half of 2018.

Our Product Candidates

MicroProst

MicroProst is our proprietary latanoprost prostaglandin micro-formulation product candidate being developed for a first-line indication therapy for CACG. Currently, there are no FDA-approved therapies for CACG, which accounts for 10% of all glaucoma in the U.S. and up to 50% of all glaucoma in China. If approved, MicroProst would be the first treatment approved for CACG.

Background of Chronic Angle Closure Glaucoma and Market Opportunity

CACG is a well characterized and clinically diagnosed disease entity, as established by the American Academy of Ophthalmology Preferred Practice Patterns. Similar to the more prevalent open-angle glaucoma, it is characterized by increased IOP and optic neuropathy. Yet, its pathophysiology is underpinned by angle closure from peripheral anterior synechiae whereby the iris is occluding the drainage outflow to the trabecular meshwork in the angle. CACG is separate from acute angle-closure glaucoma which requires immediate intervention. There are more than 581,000 CACG patients in the U.S., as shown below. We conservatively estimate the addressable market at over $700 million in the U.S. alone.

Estimated population with CACG (thousands) by region (95% CI)

	Number of CACG cases (thousands) 40 years old +			% Increase in CACG cases relative to 2010		
	UK	Europe	U.S.	UK	Europe	U.S.
2010	130 (71−211)	1600 (873−2604)	581 (309−958)	1.	•	2.
2015	141 (77−229)	1663 (902−2713)	637 (338−1047)	8.6	3.9	9.5
2020	154 (85−248)	1743 (953−2837)	687 (372−1124)	19.0	8.9	18.2
2025	160 (89−258)	1831 (1012−2967)	743 (410−1206)	23.6	14.5	27.8
2030	165 (93−265)	1934 (1082−3115)	812 (457−1304)	27.5	20.9	39.6
2040	188 (108−302)	2102 (1198−3344)	930 (532−1478)	44.9	31.4	59.9
2050	195 (112−309)	2080 (1208−3285)	973 (556−1550)	50.7	30.0	67.4

Once angle-closure glaucoma develops, it is a condition that often requires chronic treatment. The mainstay of glaucoma treatment for both open and angle-closure glaucoma is IOP lowering with pharmacologic therapy. While IOP lowering pharmacotherapies have been FDA indicated and approved for

IOP lowering in open-angle glaucoma, none have been specifically studied in FDA trials nor indicated for CACG, which is a less prevalent disease. Despite the unmet need and the fact that over 90% of CACG patients continue to require chronic lifelong IOP lowering therapy, physicians continue to use off-label treatments without the support of rigorous clinical trials and data. Therapeutic control is particularly important for CACG patients where it has been well established that optic nerve damage is more IOP-dependent than that of open-angle glaucoma and CACG patients progress two times more quickly than open-angle glaucoma patients.

There is strong clinical evidence from multiple studies as well as a more recent randomized controlled study published in the Archives of Ophthalmology that latanoprost and timolol cause significant IOP lowering in patients with CACG — 35% and 26% respectively. Even though there has been no FDA approved therapy, peer-reviewed and published clinical trials demonstrate robust therapeutic effect of latanoprost in CACG, which is highly informative for our forthcoming Phase III clinical trial. A randomized controlled study in 60 eyes published in the peer-review journal, Archives of Ophthalmology, shows not only a high level of IOP lowering effect of 8.2 mmHg at 3 month but also superiority to active timolol control which only lowered IOP by 6.1 mmHg.

Diumal Variation of Introcular Pressure (IOP) at Baseline and After 3 Months of Therapy With Latanoprost and Timolol in 60 Eyes

		Latanoprost			Timolol Maleate			
			Decrease in IOP			Decrease in IOP		
Time of IOP Recording	Mean ± SD Baseline IOP, mm Hg	Mean ± SD IOP, mm Hg	Mean ± SD, mm Hg	%	Mean ± SD IOP, mm Hg	Mean ± SD, mm Hg	%	*P* Value
7 AM	23.5 ± 3.1	14.0 ± 2.2	9.5 ± 3.3	40.4	18.3 ± 3.2	5.2 ± 3.6	22.1	<.01
10 AM	24.6 ± 3.9	14.6 ± 2.8	10.0 ± 4.3	40.6	17.9 ± 3.6	6.7 ± 3.5	27.2	<.01
1 PM	23.6 ± 2.7	16.2 ± 2.7	7.4 ± 3.4	31.4	17.1 ± 3.2	6.5 ± 3.8	27.5	.04
4 PM	23.2 ± 2.7	15.7 ± 3.4	7.5 ± 3.3	32.3	17.7 ± 3.9	5.6 ± 3.7	24.1	<.01
7 PM	22.4 ± 3.1	15.6 ± 3.1	6.8 ± 3.4	30.4	16.9 ± 3.8	5.6 ± 3.9	25.0	.01
10 PM	23.3 ± 2.9	15.6 ± 3.0	7.6 ± 3.9	32.6	16.3 ± 3.4	6.9 ± 3.6	29.6	.25
Mean	23.4 ± 2.1	15.3 ± 1.8	8.2 ± 2.0	34.9	17.4 ± 1.7	6.1 ± 1.7	26.0	<.01

Additionally, 72% of patients taking latanoprost and 43% of patients taking timolol achieved more than 30% IOP lowering from baseline. Similarly, another randomized controlled study demonstrated an 8.8 mmHg IOP reduction with latanoprost and 5.7 mmHg reduction with timolol in patients with CACG. Data from these studies not only suggest the biologic therapeutic effect of IOP lowering in CACG but also highlight the undesirable associated safety profile of macro-dosing such as hyperemia and ocular discomfort which caused significant adverse events in more than 40% of patients. Based on these studies and the data from the open-angle glaucoma disease therapeutic paradigm, we believe MicroProst may demonstrate IOP lowering and an improved safety profile for CACG patients in our planned Phase III clinical trial.

Phase III Clinical Development Program

Subsequent to the completion of our Phase II clinical trials, we met with the FDA to discuss our Phase III plans for MicroProst. The FDA outlined the necessary clinical trials for approval, and we are preparing to initiate a Phase III registration program, relying on the 505(b)(2) pathway, for a first-line therapeutic indication in CACG for MicroProst. If approved, MicroProst will be the first FDA-approved treatment for CACG. The targeted piezo-print technology will provide micro-dosing (6–8 µL) of prostaglandin latanoprost directly to the ocular surface of the cornea, which is the site of the highest intraocular penetration. We believe MicroProst will achieve similar clinical activity without the adverse effects seen with conventional drops, which overdose the eye with potentially harmful preservatives and API. This could provide additional opportunities for us to pursue follow-on expanded indications of MicroProst, such as for the treatment of open-angle glaucoma, where non-micro-therapeutic latanoprost is currently the primary therapeutic modality.

The MicroProst Phase III program will consist of two randomized controlled clinical trials in CACG with a 3-month primary end-point consisting of IOP reduction and follow-up for six months. We plan to commence the clinical trial in the second half of 2018, subject to a pre-IND meeting with the FDA in early 2018, and estimate 200 patients per clinical trial. If the primary objectives of our Phase III clinical trial are met, we plan to submit an NDA, for marketing approval of MicroProst for the treatment of CACG in the U.S. We have entered into a master licensing partnership for all of our micro-therapeutic programs, including our MicroProst program, with Senju Pharmaceuticals for Asia, including China, Japan and India.

MicroStat

MicroStat is the potentially first-in-class fixed combination micro-formulation product candidate for mydriasis (eye dilation) intended to facilitate office-based eye examinations which serve over 80 million dilated retina eye exams performed each year in the U.S. MicroStat has been designed to achieve adequate pupil dilation while reducing unintended side-effects associated with conventional mydriatic agents.

Background of Mydriasis and Market Opportunity

There are more than 80 million topical mydriatic applications performed every year as a required part of the comprehensive dilated eye exam and standard retina fundoscopy for diabetic retinopathy screening, macular degeneration evaluation, glaucoma optic disc evaluation and many other back-of-the-eye conditions. Most optometrist and ophthalmologist offices have multiple bottles of both phenylephrine and tropicamide and use each bottle on multiple patients, which carries a risk of contaminating patients' eyes and spreading infections. The bottles are purchased directly from suppliers and are not subject to insurance reimbursement. Our combination therapy, if approved, will allow the purchase of one product for eye dilation, and our system does not come in direct contact with the eye, thus minimizing the risk of infection. We believe the addressable market is over $150 million in the U.S. alone.

Most dilated eye exams require that two separate topical pharmacologic agents/drops be administered sequentially (tropicamide and phenylephrine). All current mydriatic formulations use conventional macro-dose drop delivery (30–50 µL) which significantly overdoses the ocular surface whose physiologic capacity is only 6–8 µL. Studies demonstrate that standard macro-dosed pharmacologic dilation is associated with significant ocular discomfort and mild-moderate eye pain. On the standard visual analogue scale for pain, such discomfort can exceed the levels of pain associated with a flu vaccine subcutaneous injection. Additionally, there are systemic safety concerns with mydriatic macro-dosing for retinopathy of prematurity retinal screening and pediatric dilated eye exams. Studies comparing micro-dosed phenylephrine and cyclopentolate to traditional eyedrops (30–50 µL drop size) in premature babies and in full-term infants have shown equivalent pupil dilation with drop sizes ranging from 5–8 µL while reducing systemic levels by more than 50%.

With the millions of patients exposed to mydriatic pharmacologic agents every year, we are developing a micro-dose alternative whereby targeted piezo-print technology can be deployed to reduce ocular and systemic exposure by more than 75%. This potential improvement stems from lowering the dose from the 30–50 µL in standard drops to just 8 µL with MicroStat combined with targeted delivery to the ocular surface. We expect to achieve similar mydriatic activity as drops without the high incidence of unwanted side effects.

Pharmacologic mydriasis: dilated pupil after application

Phase III Clinical Development Program

Based on our prior Phase II clinical trials and subsequent FDA feedback, we are proceeding towards the initiation of the Phase III mydriasis program for the potentially first-in-class fixed-combination, micro-formulation of phenylephrine 2.5% and tropicamide 1% (MicroStat). The MicroStat program will consist of two Phase III randomized controlled clinical trials to investigate pharmacologic dilation of our fixed combination micro-formulation versus drops of individual components (phenylephrine drops alone and tropicamide drops alone) with the primary endpoint of pupil change from baseline. We estimate 50 patients per clinical trial and are planning to commence the clinical trials in the second half of 2018. If the primary objectives of our Phase III program are met, we plan to submit an NDA to the FDA for marketing approval of MicroStat for pharmacologic mydriasis in the U.S. under the 505(b)(2) pathway. We have entered into a master licensing partnership for all of our micro-therapeutic programs, including our MicroStat program, with Senju Pharmaceuticals for Asia, including China, Japan and India.

MicroTears

MicroTears is a differentiated micro-droplet ocular surface tear replenishment product candidate for the $2 billion-plus OTC artificial tear market. Our piezo-technology enables accurate delivery directly to the ocular surface, which we believe enhances its effectiveness. The lower volume of MicroTears will also lower the incidents of droplet overflow. While no FDA studies are required for registration of a monograph formulation, we expect to conduct multiple Phase IV post-marketing studies to demonstrate the benefits of MicroTears. We plan to complete formulation and manufacturing scale-up activities for expected introduction to market in mid-to-late 2019.

Background of Dry Eye Syndrome and Market Opportunity

DES is a common ocular condition. It is a chronic, episodic, multifactorial disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. DES can have a significant impact on quality of life and can potentially cause long-term damage to the ocular surface. In addition, the vast majority of DES patients experience acute exacerbations of their symptoms, which are commonly referred to as flares, at various times throughout the year. These flares can be triggered by numerous factors, including exposure to allergens, pollution, wind and low humidity, intense visual concentration such as watching television and working at a computer, contact lens wear, smoking and sleep deprivation, which cause ocular surface inflammation and impact tear production and/or tear film stability.

Over 20 million people in the U.S. suffer from the symptoms of dry eye. Twenty-five percent of patients visiting ophthalmology clinics report dry eye symptoms. DES is a complex condition caused by a decreased tear production and/or increased tear evaporation. This can result in discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface.

While many patients receive prescriptions for dry eye symptoms, the majority opt for OTC products. The artificial tears market is expected to exceed $2.0 billion in 2018, yet all artificial tears are delivered in single or multi-dose bottles that are not highly differentiated. We believe MicroTears will offer improved accuracy in delivering artificial tears to the eye, better ocular coating, and lower incidence of tears running down the patient’s face. We believe these factors will differentiate MicroTears from eye drop versions of artificial tears.

Additional Pipeline Assets

In addition to the three late-stage development programs, we plan on leveraging our existing platform technology to continue developing other micro-therapeutic treatments for front-of-the-eye diseases that can be administered using our piezo-print technology.

We recently initiated the development of a micro-formulation of atropine for moderate to severe myopia (nearsightedness), an ocular disorder in which the optical power of the eye is too strong for the corresponding ocular anatomy. Myopia is the most common refractive error requiring correction seen in

children. While currently there are no FDA-approved therapies for myopia progression, there is growing evidence of the therapeutic activity of topical atropine, an anticholinergic agent use for dilation, as a treatment to slow progression. Despite activity, safety concerns such as pupil dilation, photosensitivity and accommodation difficulties associated with standard atropine 1% have tempered initial clinical adoption. While macro-dose atropine 1% is currently FDA-approved for pupil dilation in the U.S., its significant side effect profile has impeded clinical utility and adoption for myopia progression. If the primary objectives of our Phase III program are met, we plan to submit an NDA to the FDA for marketing approval of MicroPine to slow the progression of myopia under the 505(b)(2) pathway.

Our Technology

The piezo-print device comes in two parts:

- The base contains the electronic components which enable generation of control signals that ensure, consistent, accurate columnated arrays of micro-droplets, as well as dose tracking via Bluetooth connectivity; and
- The disposable cartridge contains the drug formulation in a primary drug container, targeted dosing system and piezo-driven ejector nozzle, and comes in one month doses.

For administration of our product candidates, the patient receives both the base and the disposable cartridge. For refills, the patient receives only the disposable cartridge. Patients deliver their dose by attaching the cartridge to the base, pressing an activation button which loads a single drug dose, then, holding it between one and two inches from the eye while looking directly into an illuminated circle, pressing a second button to emit the micro-droplet delivered medication. The micro-droplets are emitted in a quickly repeating array, that in aggregate form a micro-jet. The delivery of the full dose occurs in less than 80 milliseconds, which beats the blink reflex of the eye and enables the medication to consistently coat the ocular surface while not flooding the eye's tear capacity. The patient feels a wet sensation on the eye, but does not experience any pain, as demonstrated in studies to date. Several acute clinical trials have been performed to date that demonstrate its usability. As a precise and quick delivered micro-dose, it does not drip down the face or drain down the naso-lacrimal duct thereby minimizing delivery of extra product or preservatives to the eye. The rechargeable base has intelligent power management and precision designed circuitry that maximizes battery life allowing for infrequent recharging, while always providing consistent dose delivery over the life of each cartridge.

Our system is partially based on piezo driven printer technology, which is also used for high-precision ink jet printing. In ink jet printing, piezo technology enables ink to be sprayed with precision to form letters and numbers on paper. Our patented system takes aspects of piezo driven printer technology, and applies it to the delivery of therapeutics to the eye. Our technology has six issued U.S. patents.

Sales and Marketing

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. We have licensed commercialization rights in Asia to Senju Pharmaceuticals, and have retained global commercial rights for our product candidates in all other regions. If our product candidates receive marketing approval, we would plan to commercialize them in the United States through a combination of distributors and our own specialty sales force. We would expect to work with distribution companies or through other marketing arrangements in the EU and other regions outside the United States. We believe that the U.S. commercial organization will consist of approximately 100–125 sales and marketing professionals calling on ophthalmologists and optometrists. We would expect to make hires and sign distribution agreements for commercialization following NDA approval of any of our product candidates. Our management team and directors, which would lead the commercialization planning of our lead product candidates, have substantial experience in the commercialization of ophthalmic therapeutics.

Manufacturing

We currently rely on a combination of internal manufacturing capacity and third-party manufacturers to produce the product candidates for our clinical trials. We manage such production with all our vendors on a purchase order basis. Relationships with vendors of critical components are governed by applicable master service and supply agreements. We do not currently have long-term agreements with these manufacturers or any other third-party suppliers. We intend to procure quantities on a purchase order basis for our clinical and initial commercial production. If any of our existing third-party suppliers should become unavailable to us for any reason, we believe that there are a number of potential replacements, although we might experience a delay in our ability to obtain alternately sourced quantities of materials or services. We also do not have any current contractual relationships for the manufacture of commercial supplies of our product candidates if they are approved. With respect to commercial production of our product candidates in the future, we plan to outsource production of the majority of the product candidates if they are approved for marketing by the applicable regulatory authorities.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Our potential competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic or biosimilar drug companies. Many of our competitors have significantly greater financial and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring products, product candidates or other technologies that we may target to in-license or acquire in pursuit of our updated business plan.

For the MicroProst program, there are currently no FDA approved therapies for chronic angle closure glaucoma and we are not aware of any in ongoing FDA registration studies. Physicians currently use off-label IOP lowering medications that are FDA-approved for a different disease entity, namely open-angle glaucoma.

For MicroStat, we are not aware of any micro-therapeutics nor of any existing phenylephrine-tropicamide topical fixed combination even in standard macro-dose. There are competitive macro-dose drop formulations of individual therapeutics such as phenylephrine and tropicamide for mydriasis by companies such as Akorn, Alcon and others.

For MicroPine, we are not aware of any FDA-approved therapies to slow the progression of myopia.

For MicroTears, there is a $2 billion market of multiple competitive artificial tear products, but none that we are aware with targeted, ocular surface coating micro-droplet delivery. We believe the simplicity and convenience of our MicroTears system, which can be administered without tilting the head and with minimal risk of inconveniences such as dripping down the patient's cheek, will differentiate our product from other artificial tears.

Intellectual Property

Our success may depend on our ability to obtain, maintain and enforce our proprietary rights related to our products and other technologies. We must also operate without infringing the proprietary rights of others while preventing others from infringing our proprietary rights. We will seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications. We may also rely on trade secrets and know-how for some proprietary methods, methods of manufacture and systems and devices. We continue innovating our technologies, and will file appropriate U.S. and foreign applications for our future innovations.

Patents

As of October 6, 2017, we owned five U.S. issued utility patents, one issued design patent, and eleven pending U.S. patent applications, as well as twenty-five foreign issued and allowed patents and sixty-one foreign patent applications (including Patent Cooperation Treaty, or PCT, applications).

Exemplary patent coverage within the portfolio includes issued and pending patent application disclosing and claiming the following devices and methods:

- A piezoelectric device configured to generate an ejected stream of droplets is the subject of one patent family. The device ejects droplets having an average ejected droplet diameter greater than 20 microns and an average initial droplet ejecting velocity between 0.5 m/s and 10 m/s. Furthermore, the stream of droplets is generated with low entrained airflow so that at least 75% of the mass is deposited on the eye. U.S. patent(s) for these devices are expected to expire in 2031.
- A method of delivering a medicament or solution to an eye with a piezo-ejector device is the subject of another patent family. The method involves delivering an average droplet size of 20 microns to 100 microns in diameter with an average initial droplet ejecting velocity between 1 m/s and 10 m/s to the eye. About 85% to 100% of the ejected mass of droplets is deposited on the eye. U.S. patent(s) for these methods are expected to expire in 2031.
- A device having a piezo-ejector that generates a directed stream of droplets through specially shaped openings in the piezo-ejector is the subject of still another patent family. The openings provide laminar flow through the openings. Laminar flow is provided by shaping the openings with a gradual slope change so that an external entry radius has a circular shape which reduces airflow while providing laminar flow through the openings. U.S. patent(s) related to these devices are expected to expire in 2033.
- A piezo-electric ejector device having a microcontroller which auto-tunes the ejector mechanism is the subject of a yet another patent family. The device generates at least one cycle in a range of drive signal frequencies and obtains time-energy product feedback from a decay signal emitted by the actuator. U.S. patent(s) related to these devices are expected to expire in 2033.
- A method of monitoring the treatment of ophthalmic subjects by capturing images of the eye is the subject of another patent family. Images of the eye are taken which are sufficient to obtain information about the diagnosis or health of the eye. The data is stored and analyzed to monitor treatment. U.S. patent(s) related to this method are expected to expire in 2031.
- A fluid ejector having a fluid loading plate in parallel arrangement with an ejector mechanism is the subject of patent family patented in Europe. The fluid loading plate forms a capillary separation with the ejector mechanism to generate capillary fluid flow therebetween. The fluid loading plate is also attached to the reservoir (at a fluid reservoir interface) and to the ejector

mechanism (at an ejector mechanism interface) and may have one or more fluid channels from the fluid reservoir interface to the ejector mechanism interface. The ejector produces a stream of droplets having a droplet diameter greater than 15 microns with the stream having low entrained airflow so that the pressure of the stream will be substantially imperceptible.

The term of any patent depends upon the legal term for patents in that particular country. In the U.S., the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in any country. In the U.S., a patent's term may be lengthened by patent term adjustment which compensates a patentee for administrative delays by the USPTO in examining and granting a patent. A patent term may also be shortened if a patent is terminally disclaimed over another patent or application.

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permit a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension. Similar patent term extension/reduction provisions are available in the European Union and other jurisdictions. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we will apply for patent term extensions on issued patents covering our products to the extent available under the applicable law, depending upon the length of any such clinical trials for any product and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us. However, we cannot provide any assurances that any such patent term extension of a foreign patent will be obtained and, if obtained, the duration of such extension.

Proprietary Technology

In addition to patents, we may rely on trade secrets and proprietary know-how to protect our technology. We will protect our proprietary technology and processes in the appropriate manner to maintain their secrecy including confidentiality agreements when dealing with third parties. We will also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. We shall also require invention assignment agreements with our employees, consultants, and contractors.

Government Regulation and Product Approvals

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the U.S.

In the U.S., the FDA regulates drug products under the FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources The failure to comply with applicable requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, voluntary product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the U.S. must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the clinical trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that clinical trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a

delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with FDA certain regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, such studies must be conducted in accordance with good clinical practice, or GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a clinical trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

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

- *Phase 3.* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2018 is $2,421,495 for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual prescription drug program fee, which for fiscal year 2018 is $304,162. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation and a waiver for certain small businesses.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. For applications of drug products that are not new molecular entities, FDA aims to conduct standard reviews within 10 months of receipt of the NDA and priority reviews within 6 months of receipt of the NDA. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished

drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are

subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical trials which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform

additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug..."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Clinicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied;

rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension, in connection with any of our product candidates.

The 21st Century Cures Act

On December 13, 2016, President Obama signed the 21st Century Cures Act, or Cures Act, into law. The Cures Act is designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorizes increased funding for the FDA to spend on innovation projects. The new law also amends the Public Health Service Act to reauthorize and expand funding for the NIH. The Act establishes the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early stage investigators and research. It also charges NIH with leading and coordinating expanded pediatric research. Further, the Cures Act directs the Centers for Disease Control and Prevention to expand surveillance of neurological diseases.

With amendments to the FDCA and the Public Health Service Act, or PHSA, Title III of the Cures Act seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorizes the existing priority review voucher program for certain drugs intended to treat rare pediatric diseases until 2020; creates a new priority review voucher program for drug applications determined to be material national security threat medical countermeasure applications; revises the FDCA to streamline review of combination product applications; requires FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provides a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorizes FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the U.S., a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and

jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Procedures Governing Approval of Drug Products in the European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Within this framework, manufacturers may seek approval of hybrid medicinal products under Article 10(3) of Directive 2001/83/EC. Hybrid applications rely, in part, on information and data from a reference product and new data from appropriate preclinical tests and clinical trials. Such applications are necessary when the proposed product does not meet the strict definition of a generic medicinal product, or

bioavailability studies cannot be used to demonstrate bioequivalence, or there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic product compared to the reference medicinal product. In such cases the results of tests and clinical trials must be consistent with the data content standards required in the Annex to the Directive 2001/83/EC, as amended by Directive 2003/63/EC.

Hybrid medicinal product applications have automatic access to the centralized procedure when the reference product was authorized for marketing via that procedure. Where the reference product was authorized via the decentralized procedure, a hybrid application may be accepted for consideration under the centralized procedure if the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation, or the granting of a community authorization for the medicinal product is in the interest of patients at the community level.

Clinical Trial Approval in the European Union

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, or GCP, are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the E.U. member states. Under this system, approval must be obtained from the competent national authority of each E.U. member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the E.U. passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the E.U. portal; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I is assessed jointly by all member states concerned, and Part II is assessed separately by each member state concerned); strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Periods of Authorization and Renewals

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year

renewal. Any authorization which is not followed by the actual placing of the drug on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Data and Market Exclusivity in the European Union

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company can complete a full MAA with a complete database of pharmaceutical test, preclinical tests and clinical trials and obtain marketing approval of its product.

Regulatory Requirements after Marketing Authorization

As in the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of the manufacturing and marketing authorizations. The holder of an EU marketing authorization for a medicinal product must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. The manufacturing process for medicinal products in the European Union is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, including compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients.

In the European Union, the advertising and promotion of approved products are subject to EU Member States' laws governing promotion of medicinal products, interactions with clinicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the European Union.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the U.S., ensuring adequate coverage and payment for our product candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to clinicians and teaching hospitals and clinician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been several federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the U.S.

In March 2010, the U.S. Congress enacted the Affordable Care Act, or ACA, which, among other things, includes changes to the coverage and payment for products under government healthcare programs. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. The ACA provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, 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.

With the new Administration and Congress, there may be additional legislative changes, including potentially repeal and replacement of certain provisions of the ACA. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation will provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. It is possible that any repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions.

MANAGEMENT

Set forth below is information regarding our current directors, director nominees and executive officers. Each director holds his office until he resigns or is removed and his successor is elected and qualified.

Name	Age	Position
Tsontcho Ianchulev, M.D., M.P.H.	44	Chief Executive Officer, Chief Medical Officer and Director
Jennifer "Ginger" Clasby	64	Vice President, Clinical Operations
Luke Clauson	39	Vice President, Research & Development
Curt LaBelle, M.D., M.B.A	47	Director
Fred Eshelman, Pharm.D.	69	Director and Chairman
Ernest Mario, Ph.D.	79	Director
Shuhei Yoshida	45	Director

Executive Officers

Dr. Tsontcho Ianchulev has been serving as our Chief Executive Officer, Chief Medical Officer and a member of our Board of Directors since inception. From 2009 to February 2016, he was the chief medical officer and the head of technology and business development for Transcend Medical (acquired by Alcon/Novartis). Prior to that, while at Genentech, Inc., Dr. Ianchulev headed the ophthalmology research group and directed the development and the FDA approval of Lucentis. Dr. Ianchulev received his bachelor of science from the University of Rochester. Dr. Ianchulev received both his medical degree and a master's of public health from Harvard University and completed his specialty training at the Doheny Eye Institute, University of Southern California. Currently, Dr. Ianchulev serves as a professor in the New York Eye and Ear Infirmary of Mount Sinai. We believe Dr. Ianchulev's experience in drug discovery and development of pharmaceutical products and in the operation of biopharmaceutical businesses is valuable to our board and our company.

Jennifer "Ginger" Clasby has worked in the field of regulated medical products during most of her career. She has been serving as our Vice President, Clinical Operations since September 2017. From 2009 to May 2016, she served as Vice President, Clinical & Regulatory Affairs/Quality Assurance at Transcend Medical, an early-stage, venture-backed company developing novel products for management of glaucoma, which was acquired by Alcon. In that position, she was responsible for overseeing clinical operations and regulatory processes for the company's clinical trials in the US, Europe and Latin America, as well as worldwide regulatory affairs, quality assurance and compliance activities. Previously, Ms. Clasby worked with ophthalmic device companies American Medical Optics and Optical Radiation Corporation in various roles in the areas of Clinical Affairs, Manufacturing Operations and Marketing/Sales. She was also a pivotal executive with Promedica International, a contract research organization, from 1994 to 2009. She serves on the University of California-Irvine Extension Life Science Advisory Committee. She holds an MS degree in Industrial Engineering from Arizona State University and BS degrees in Mathematics & Physics from Guilford College.

Luke Clauson has been serving as our Vice President, Research & Development since April 2017. From 2009 to March 2016, Mr. Clauson was Vice President, Research & Development and Operations at Transcend Medical, which developed a micro-stent for glaucoma and was acquired by Alcon. He started his engineering career at Cardica, where he eventually directed product development for the core anastomotic business. He founded a medical device-focused engineering development company, Innovative Drive Corporation, that has helped businesses of all sizes conceptualize and bring dozens of products to market, including several in ophthalmology. Mr. Clauson has extensive experience in designing, validating, achieving regulatory approval and scaling for commercialization with multiple products. He holds a bachelor of science in mechanical engineering degree from the University of California, Davis.

Non-Employee Directors

Dr. Curt LaBelle has been serving as a member of our Board of Directors since December 2014. Dr. LaBelle previously served as a member of the board of directors of Sirion Therapeutics, Inc., a company that developed Durezol for ophthalmic post-operative inflammation (acquired by Alcon, Inc.) and Zirgan for ocular herpetic keratitis (acquired by Bausch & Lomb Holdings, Inc.), as well as a development program for a topical vancomycin for serious eye infections (acquired by Perrigo Company plc). He is the managing partner of the Global Health Investment Fund (July 2015–current) and was previously a managing director at Tullis Health Investors Inc. (2008–2015). Dr. LaBelle has served as chairman of the board of Impulse Monitoring (acquired by NuVasive, Inc.), Exagen Diagnostics, and SafeOp Surgical, Ins. He was also a Board member at KAI Pharmaceuticals, a pharmaceutical company developing drugs for patients with chronic kidney disease which was sold to Amgen Inc. in 2012, and TransMolecular, Inc., a neuroscience biotechnology company developing products to treat central nervous system disorders which was sold to Morphotek, Inc. in 2011. He has also served in board or other advisory capacities with Coherex Medical, Inc. (sold to J&J), Endoscopic Technologies, Inc. d/b/a Estech (sold to AtriCure) and Vidacare (sold to Teleflex), among others. Dr. LaBelle holds M.D. and M.B.A. degrees from Columbia University and a B.S. in Economics from Brigham Young University. Dr. LaBelle's extensive experience serving as a venture capitalist and board member to numerous companies in the healthcare industry is valuable to our board and our company.

Dr. Fred Eshelman has been serving as a member of our Board of Directors since December 2014. He has more than 35 years of strategic development, executive, operational and financial leadership experience in the pharmaceutical and healthcare industries. Dr. Eshelman was the founder of Pharmaceutical Product Development, Inc. and founding chairman of Furiex Pharmaceuticals, Inc. In 2014, Dr. Eshelman founded Eshelman Ventures, LLC, an investment company focused on healthcare companies. From 2009 to 2014, Dr. Eshelman served as chairman of the Board of Furiex. Since September, 2015, he has been serving as chairman of The Medicines Company. From 2009 to 2011, he served as executive chairman of Pharmaceutical Product Development, Inc. He also served as chief executive officer of Pharmaceutical Product Development, Inc. from 1990 to 2009 and as vice chairman of its Board of Directors from 1993 to 2009. Dr. Eshelman currently serves on the board of directors of Valeant Pharmaceuticals International, Inc. and G1 Therapeutics, Inc. Dr. Eshelman received a bachelor's degree in pharmacy from UNC Chapel Hill and a doctorate in pharmacy from the University of Cincinnati, and he completed an OPM program at Harvard University. Dr. Eshelman also received an honorary doctor of science from UNC Chapel Hill. We believe Dr. Eshelman's experience in drug discovery and development of pharmaceutical products and in strategic planning at a variety of biopharmaceutical companies is of considerable importance and is valuable to our board and our company.

Dr. Ernest Mario has been serving as a member of our Board of Directors since December 2014. Between September 2010 and October 2011, Dr. Mario served as a director of Tonix Sub. Dr. Mario is a former deputy chairman and chief executive of Glaxo Holdings plc and former chairman and chief executive officer of ALZA Corporation. Since April 2014, Dr. Mario has served as Chairman of Soleno Therapeutics, Inc. (formerly Capnia, Inc.), a specialty pharmaceutical company in Palo Alto, CA. Between August 2007 and February 2014, Dr. Mario served as the chief executive officer and chairman of Soleno Therapeutics, Inc. and between February 2014 and April 2014, Dr. Mario served as executive chairman. From 2003 to 2007, he was chairman and chief executive officer of Reliant Pharmaceuticals, Inc. Dr. Mario is currently a director of Soleno Therapeutics, Inc. (since 2007), Celgene Corp. (since 2007) and Chimerix, Inc. (since February 2013). Dr. Mario is also chairman of Chimerix. Dr. Mario served as a director of Boston Scientific Corp. (2001–2016), Kindred Biosciences, Inc. (2013–2016), VIVUS Inc. (2012–2013), XenoPort Inc. (2012–2015), and Maxygen Inc. (2001–2013). He serves as an advisor to The Ernest Mario School of Pharmacy at Rutgers University. In 2007, Dr. Mario was awarded the Remington Medal by the American Pharmacists' Association, pharmacy's highest honor. Dr. Mario received a Ph.D. and an M.S. in physical sciences from the University of Rhode Island and a B.S. in pharmacy from Rutgers University. Dr. Mario brings significant executive leadership experience, including his experience leading several pharmaceutical companies and extensive experience in financial and operations management, risk oversight, and quality and business strategy and thus, is valuable to our board and company.

Shuhei Yoshida has been serving as member of our Board of Directors since December 2014. Mr. Yoshida has extensive executive and operational experience in the international pharmaceutical industry. Mr. Yoshida is the executive vice president and head of Corporate Strategic Planning at Senju Pharmaceutical Co., Ltd., a leading, privately owned specialty pharmaceutical research, development, manufacturing and sales company located in Osaka, Japan, with global subsidiaries, branch offices and joint venture relationships throughout the world, including in the U.S., Canada, South America, Europe, Middle East, Asia and Africa. Mr. Yoshida's experience in pharmaceutical industry makes him valuable to our board and company.

Family Relationships

None of our officers and directors have any family relationship.

Indemnification of Directors and Officers

Our Certificate of Incorporation, as amended, and Bylaws both provide for the indemnification of our officers and directors to the fullest extent permitted by Delaware law.

Election of Directors and Officers

Directors are elected to serve until the next annual meeting of stockholders and until their successors have been elected and qualified. Officers are appointed to serve until the meeting of the Board of Directors following the next annual meeting of stockholders and until their successors have been elected and qualified.

Involvement in Certain Legal Proceedings

Our Chief Executive Officer, Dr. Ianchulev, and two members of our Board of Directors, Dr. Ernest and Dr. Eshelman, are named as defendants in a legal proceeding filed in the United States District Court for the District of New Jersey on September 2, 2014 that has not yet been fully resolved in connection with our asset purchase from Corinthian Opthalmic, Inc. A shareholder of Corinthian, alleging a fraudulent transfer, is seeking to recover the purchase price of its Corinthian shares and other damages in the aggregate amount of approximately $1.1 million. A settlement conference was conducted on July 24, 2017, however, the parties are not close to agreement on a settlement. On October 10, 2017, the Court denied each party's motion for summary judgment. The Company has filed a motion for reconsideration of the Court's decision, with particular focus on the dismissal of the claim against the Company. The motion for reconsideration will be heard on November 20, 2017. A pretrial conference is scheduled with the Court for December 18, 2017. We are indemnified by Corinthian in this litigation and Corinthian's applicable insurance policy provides coverage of $10,000,000. As a result, we do not expect to incur a material loss as a result of this litigation.

No executive officer, director or director nominee of ours has been convicted in any criminal proceeding (excluding traffic violations) or is the subject of a criminal proceeding which is currently pending.

No executive officer, director or director nominee of ours has been the subject of any order, judgment, or decree of any court of competent jurisdiction, or any regulatory agency permanently or temporarily enjoining, barring suspending or otherwise limiting him/her from acting as an investment advisor, underwriter, broker or dealer in the securities industry, or as an affiliated person, director or employee of an investment company, bank, savings and loan association, or insurance company or from engaging in or continuing any conduct or practice in connection with any such activity or in connection with the purchase or sale of any securities. Other than disclosed above, no executive officer, director or director nominee of ours is the subject of any pending legal proceedings.

Director Independence and Board Committees

Director Independence

Of our current directors, our Board of Directors has determined that Dr. Eshelman, Dr. Mario and _____ are "independent" under the Nasdaq listing rules, which is defined generally as a person other than

an officer or employee of the company or its subsidiaries or any other individual having a relationship, which, in the opinion of our Board of Directors would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director.

Our independent directors will have regularly scheduled meetings at which only independent directors are present.

Any affiliated transactions will be on terms no less favorable to us than could be obtained from independent parties. Our Board of Directors will review and approve all affiliated transactions with any interested director abstaining from such review and approval.

Board Committees

Our Board of Directors has established two standing committees — Audit and Compensation. All standing committees operate under a charter that has been approved by our Board of Directors.

Audit Committee

Our Board of Directors has an Audit Committee, composed of Dr. Eshelman, Dr. Mario and _____, each of whom are independent directors as defined in accordance with section Rule 10A-3 of the Exchange Act and Nasdaq listing rules. _____ serves as chairman of the committee. The Board of Directors has determined that _____ is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. The Audit Committee's duties, which are specified in our Audit Committee Charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our Form 10-K;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies; and
- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.

The Audit Committee has a charter, which will be reviewed annually.

Compensation Committee

Our Board of Directors has a Compensation Committee composed of Dr. Eshelman, Dr. Mario and _____, each of whom are independent in accordance with Nasdaq listing rules. _____ will serve as the chairman of the committee upon the consummation of this offering. The Compensation Committee's duties, which are specified in our Compensation Committee Charter, include, but are not limited to:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;
- reviewing and approving the compensation of all of our other executive officers;
- reviewing our executive compensation policies and plans;
- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our executive officers and employees;
- if required, producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

The Compensation Committee has a charter, which will be reviewed annually.

Nominating and Corporate Governance Committee

We do not have a standing nominating committee. In accordance with Rule 5605(e)(1)(A) of the Nasdaq listing rules, a majority of the independent directors may recommend a director nominee for selection by the Board of Directors. The Board of Directors believes that the independent directors can satisfactorily carry out the responsibility of properly selecting or approving director nominees without the formation of a standing nominating committee. As there is no standing nominating committee, we do not have a nominating committee charter in place.

The Board of Directors will also consider director candidates recommended for nomination by our stockholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of stockholders (or, if applicable, a special meeting of stockholders). Our stockholders that wish to nominate a director for election to the Board of Directors should follow the procedures set forth in our bylaws.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the Board of Directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Code of Business Conduct and Ethics and Insider Trading Policy

We have adopted a written code of business conduct and ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions, and agents and representatives. The full text of our code of business conduct and ethics will be posted on our website at *http://www.eyenoviabio.com/*. The nominating and corporate governance committee of our board of directors will be responsible for overseeing our code of business conduct and ethics and any waivers

applicable to any director, executive officer or employee. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and agents and representatives, on our website identified above.

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EXECUTIVE COMPENSATION

The following discussion relates to the compensation of our Chief Executive Officer and Chief Medical Officer, Tsontcho Ianchulev, for fiscal years 2015 and 2016.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers for the years ended December 31, 2015 and 2016, respectively.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option awards ($)[1]	All other compensation ($)	Total ($)
Tsontcho Ianchulev	2016	$265,600[2]	—	—	—	$265,600
Chief Executive Officer and Chief Medical Officer	2015	$144,000[2]	—	$211,700[3][4]	—	$355,700

(1) The amounts reported in the "Option awards" column reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of FASB ASC Topic 718. See Note 9 to our financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.

(2) Tsontcho Ianchulev and Curt LaBelle, a member of our Board of Directors, are both partners in Private Medical Equity, Inc. We entered into a consulting agreement with Private Medical Equity, Inc. on November 4, 2014 pursuant to which we pay $33,200 per month to Private Medical Equity, Inc. in consulting fees for general management and strategy services. During the years ended December 31, 2016 and 2015, we incurred aggregate expenses of $398,400 and $398,400, respectively, related to our agreement with Private Medical Equity, Inc., of which, $265,600 and $144,000, respectively, was compensation attributable to Tsontcho Ianchulev.

(3) During 2015, we granted an option to purchase 150,000 shares of common stock at an exercise price of $0.33 per share to Tsontcho Ianchulev. The option had a grant date value of $43,400.

(4) In addition to the option grant to Tsontcho Ianchulev directly, during 2015, we granted an option to purchase 1,050,000 shares of common stock at an exercise price of $0.33 per share to Private Medical Equity, Inc. The option had a grant date value of $336,600, 50% of which, or $168,300, is attributable to Tsontcho Ianchulev.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees.

Dr. Tsontcho Ianchulev

Tsontcho Ianchulev and Curt LaBelle, a member of our Board of Directors, are both partners in Private Medical Equity, Inc. We entered into a consulting agreement with Private Medical Equity, Inc. on November 4, 2014 pursuant to which we pay of $33,200 per month to Private Medical Equity, Inc. in consulting fees for general management and strategy services. During the years ended December 31, 2016 and 2015, we incurred aggregate expenses of $398,400 and $398,400, respectively, related to our agreement with Private Medical Equity, Inc.

We entered into an engagement letter with Dr. Tsontcho Ianchulev dated as of July 6, 2017. Prior to entering into this engagement letter, Dr. Ianchulev served as our Chief Executive Officer and Chief Medical Officer and was compensated by his relationship to Private Medical Equity. See "Certain Relationships and Related Party Transactions" for additional details. Under the terms of the engagement letter, Dr. Ianchulev continues to serve as the Chief Executive Officer and Chief Medical Officer. Starting July 1, 2017, he will be entitled to receive a monthly salary of $32,083, in addition to benefits available to similarly-situated employees. He will also be entitled to receive options to purchase 1,503,960 shares of our common stock under our 2014 Stock Plan. Dr. Ianchulev's engagement letter further provides that he will be bound by the terms of our standard employee nondisclosure and assignment agreement.

Jennifer "Ginger" Clasby

We entered into an engagement letter with Jennifer "Ginger" Clasby dated as of July 6, 2017. Pursuant to the terms of the engagement letter, starting on August 1, 2017, Ms. Clasby served as our Vice President, Clinical Operations on a part time basis for two days a week for a salary of $9,167 per month and $175 per hour for any additional work. Commencing late 2017 or early 2018, we have the option to engage Ms. Clasby as a full time employee with a base salary of $275,000 per year. In addition, she is granted options to purchase 300,792 shares of our common stock, 75% of which vests in equal monthly installments over 36 months starting from the date of grant and 25% of which vests in equal monthly installments over 12 months upon certain milestone. If, following a change in control, her employment is terminated without cause, and provided she signs a general release within thirty (30) days of such termination, she is entitled to receive severance payments at her final base salary rate, less applicable withholding, for a six (6) month period.

Luke Clauson

We entered into an engagement letter with Luke Clauson dated as of July 6, 2017. Pursuant to the terms of the engagement letter, starting on August 1, 2017, Mr. Clauson served as our Vice President, Research and Development on a part time basis for two days a week for a salary of $9,167 per month and $175 per hour for any additional work. Commencing late 2017 or early 2018, we have the option to engage Mr. Clauson as a full time employee with a base salary of $275,000 per year. In addition, he is granted options to purchase 375,990 shares of our common stock, 75% of which vests in equal monthly installments over 36 months starting from the date of grant and 25% of which vests in equal monthly installments over 12 months upon certain milestone. If, following a change in control, his employment is terminated without cause, and provided he signs a general release within thirty (30) days of such termination, he is entitled to receive severance payments at his final base salary rate, less applicable withholding, for a six (6) month period.

Indemnification Agreements

We intend to enter into indemnification agreements with our directors and executive officers that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

Eyenovia, Inc. 2014 Stock Incentive Plan

Our 2014 Equity Incentive Plan, or 2014 Plan, was adopted on December 14, 2014 and amended by our Board of Directors in August 2016 for the purpose of furthering our growth, development and success by offering employees, directors and consultants a continuing equity interest in our company. The Plan authorizes grants of options, stock appreciation rights, restricted stocks and restricted stock units.

Under the terms of the 2014 Plan, as amended, a committee designated by our Board of Directors was authorized to issue up to 6,500,000 shares of our common stock underlying grants under the 2014 Plan. The number and kind of awards outstanding, and made available for future grants, would have been automatically adjusted in the event of a stock dividend, stock split, reverse stock split, share combination or exchange, recapitalization, a merger or consolidation or any other similar occurrence.

Employees, directors and consultants of our Company and our affiliates are eligible to receive grants under our 2014 Plan. The exercise price of any options or stock appreciation rights may not be less than 100% of the fair market value of the common stock. Options and stock appreciation rights may only be exercised while the participant remains an employee, director or consultant, unless otherwise allowed by the committee.

The 2014 Plan may be amended by our Board of Directors in its sole discretion, retroactively or otherwise but such amendments may not materially affect any outstanding grant under the 2014 Plan without the consent of the recipient of such grant.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information regarding all outstanding stock options and restricted stock held by each of our named executive officers as of December 31, 2016:

	Option Awards				
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards; Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Tsontcho Ianchulev	675,000[1]	—	—	$ 0.33	03/23/2025

(1) Includes an option to purchase 1,050,000 shares of common stock at an exercise price of $0.33 per share issued to Private Medical Equity, Inc. Tsontcho Ianchulev and Curt LaBelle are both partners in Private Medical Equity, Inc. As a result, the option is allocated equally to each of Tsontcho Ianchulev and Curt LaBelle.

Changes in Control

There are no arrangements, known to the Company, including any pledge by any person of securities of the Company, the operation of which may at a subsequent date result in a change in control of the Company.

Compensation of Directors

None of our directors received any compensation for the fiscal year ended December 31, 2016, with the exception of Curt LaBelle, who was compensated through his relationship to Private Medical Equity. In addition, he entered into a consulting agreement with us on July 6, 2017 through Cura Partners, to provide consulting services not to exceed 2 days a week. He is entitled to receive $9,567 per month and $250 per hour for any additional work. In addition, he was granted options to purchase 500,000 shares of our common stock, 75% of which vests in equal monthly installments over 36 months starting from the date of grant and 25% of which vests in equal monthly installments over 12 months upon certain milestone. We may terminate such engagement upon 120 days' notice or immediately for cause. Since July 2016, we have paid $3,000 per month to a company controlled by Curt LaBelle for office space in New York, New York for our principal office. During the years ended December 31, 2016 and 2015, we recorded rent expense of $18,000 and $0, respectively, for the office space. See "Certain Relationships and Related Party Transactions" for additional details.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the executive officer and director compensation arrangements discussed above under "Management — Non-Employee Director Compensation" and "Executive Compensation," below we describe transactions since our inception to which we have been or will be a participant, in which the amount involved in the transaction exceeds or will exceed $120,000 and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

In October 2014, we issued and sold 1,750,000 shares of common stock to Private Medical Equity, Inc., an entity owned by Tsontcho Ianchulev, our Chief Executive Officer and Chief Medical Officer, and Curt LaBelle, a member of our Board of Directors, for $0.0001 per share.

In October 2014, we issued and sold 1,750,000 shares of common stock to PointGuard Partners, LLC, a stockholder of more than 5% of our outstanding common stock, for $0.0001 per share.

Tsontcho Ianchulev, our Chief Executive Officer and Chief Medical Officer, and Curt LaBelle, a member of our Board of Directors, are both partners in Private Medical Equity, Inc. We entered into a consulting agreement with Private Medical Equity, Inc. on November 4, 2014 pursuant to which we pay of $33,200 per month to Private Medical Equity, Inc. in consulting fees for general management and strategy services. During the years ended December 31, 2016 and 2015, we incurred aggregate expenses of $398,400 and $398,400, respectively, related to our agreement with Private Medical Equity, Inc.

PointGuard Partners, LLC, a stockholder of more than 5% of our outstanding common stock, entered into a consulting agreement with us for research and development services. During the years ended December 31, 2016 and 2015, we incurred aggregate expenses of $366,209 and $407,613, respectively, under the consulting agreement.

Since July 2016, we have paid $3,000 per month to a company controlled by Curt LaBelle for office space in New York, New York for our principal office. During the years ended December 31, 2016 and 2015, we recorded rent expense of $18,000 and $0, respectively, for the office space. In addition, he entered into a consulting agreement with us on July 6, 2017 through Cura Partners, to provide consulting services not to exceed 2 days a week. He is entitled to receive $9,567 per month and $250 per hour for any additional work. In addition, he is granted options to purchase 500,000 shares of our common stock, 75% of which vests in equal monthly installments over 36 months starting from the date of grant and 25% of which vests in equal monthly installments over 12 months upon certain milestone.

We intend to enter into indemnification agreements with our directors and executive officers that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

Statement of Policy

All future transactions between us and our officers, directors or 5% stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, during the past three fiscal years, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information concerning the ownership of our common stock as of the date of November 15, 2017, with respect to: (i) each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our common stock; (ii) all directors; (iii) all named executive officers; and (iv) all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC that deem shares to be beneficially owned by any person who has voting or investment power with respect to such shares. Shares of common stock subject to options or warrants that are exercisable as of November 15, 2017 or are exercisable within 60 days of such date are deemed to be outstanding and to be beneficially owned by the person holding such securities for the purpose of calculating the percentage ownership of such person but are not treated as outstanding for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted below, the address for each person or entity listed in the table is c/o Evenovia Inc., 501 Fifth Avenue, Suite 1404, New York, NY 10017.

	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned After this Offering	
Name of Beneficial Owner	**Number**	**Percentage[1]**	**Number**	**Percentage[2]**
Tsontcho Ianchulev[3]	5,290,581	17.3%		
Jennifer "Ginger" Clasby[4]	50,132	*		
Luke Clauson[5]	62,665	*		
Curt LaBelle[6]	5,090,447	16.8%		
Fred Eshelman[7]	4,928,171	15.9%		
Ernest Mario[8]	747,761	2.7%		
Shuhei Yoshida[9]	6,282,121	18.9%		
All directors and executive officers as a group (7 persons)[16]	**17,594,764**	**42.2%**		
5% Stockholders:				
Senju Pharmaceuticals Co., Ltd.[10]	6,069,621	18.3%		
Private Medical Equity, Inc.[11]	2,800,000	10.0%		
PME Investor Services Eyenovia, LLC[12]	2,057,114	7.1%		
PointGuard Partners, LLC[13]	1,750,000	6.5%		
John J. Mack[14]	1,703,494	6.1%		
Barry Butler[15]	4,175,000	15.1%		

* Less than 1%.

(1) Applicable percentages based on 9,624,488 shares of common stock outstanding as of November 15, 2017, and giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 17,400,772 shares of common stock upon completion of this offering. Percentages do not include any shares of common stock issued in this offering.

(2) Applicable percentages are based on _____ shares outstanding which assumes the automatic conversion of our preferred stock and the issuance of _____ shares of common stock in this offering (assuming an initial public offering price of $_____ per share, the midpoint of the price range set forth on the cover page of this prospectus). The percentage ownership information assumes no exercise of the underwriters' over-allotment option to purchase additional shares.

(3) Tsontcho Ianchulev is our Chief Executive Officer. Includes (i) 32,807 shares of common stock and 400,660 shares underlying options held by Tsontcho Ianchulev directly that are exercisable within 60 days of November 15, 2017, (ii) 1,750,000 shares of common stock and 1,050,000 shares of common stock underlying options held by Private Medical Equity, Inc. that are exercisable within 60 days of November 15, 2017 and (iii) 1,700,000 shares of common stock underlying Series A

preferred stock and 357,114 shares of common stock underlying Series B preferred stock held by PME Investor Services Eyenovia, LLC. Tsontcho Ianchulev is one of the two principal shareholders of Private Medical Equity, Inc. and a manager of PME Investor Services Eyenovia, LLC and therefore, may be deemed to have beneficial ownership of the shares of common stock held by Private Medical Equity, Inc. and PME Investor Services Eyenovia, LLC.

(4) Jennifer "Ginger" Clasby is our Vice President, Clinical Operations. Includes 50,132 shares of common stock underlying options that are exercisable within 60 days of November 15, 2017.

(5) Luke Clauson is our Vice President, Research and Development. Includes 62,665 shares of common stock underlying options that are exercisable within 60 days of November 15, 2017.

(6) Curt LaBelle is a member of our Board of Directors. Includes (i) 233,333 shares of common stock underlying options held by Curt LaBelle directly that are exercisable within 60 days of November 15, 2017., 2017, (ii) 1,750,000 shares of common stock and 1,050,000 shares of common stock underlying options held by Private Medical Equity, Inc. that are exercisable within 60 days of November 15, 2017 and (iii) 1,700,000 shares of common stock underlying Series A preferred stock and 357,114 shares of common stock underlying Series B preferred stock held by PME Investor Services Eyenovia, LLC. Curt LaBelle is one of the two principal shareholders of Private Medical Equity, Inc. and a manager of PME Investor Services Eyenovia, LLC and therefore, may be deemed to have beneficial ownership of the shares of common stock held by Private Medical Equity, Inc. and PME Investor Services Eyenovia, LLC.

(7) Fred Eshelman is a member of our Board of Directors. Includes (i) 904,074 shares of common stock, 2,154,196 shares of common stock underlying Series A preferred stock, 460,835 shares of common stock underlying Series B preferred stock and 212,500 shares underlying options held by Fred Eshelman directly that are exercisable within 60 days of November 15, 2017 and (ii) 168,750 shares of common stock underlying Series A preferred stock, 816,950 shares of common stock underlying Series A-2 preferred stock and 210,866 shares of common stock underlying Series B preferred stock held by Eshelman Ventures LLC. Fred Eshelman is the manager of Eshelman Ventures LLC and therefore, may be deemed to have beneficial ownership of the shares of common stock held by Eshelman Ventures LLC.

(8) Ernest Mario is a member of our Board of Directors. Includes 257,067 shares of common stock, 168,750 shares of common stock underlying Series A preferred stock, 109,444 shares of common stock underlying Series B preferred stock and 212,500 shares underlying options that are exercisable within 60 days of November 15, 2017.

(9) Shuhei Yoshida is a member of our Board of Directors. Includes 212,500 shares of common stock underlying options exercisable within 60 days of November 15, 2017.

(10) Includes 5,000,000 shares of common stock underlying Series A preferred stock and 1,069,621 shares of common stock underlying Series B preferred stock. Senju Pharmaceuticals Co., Ltd. is owned by the family of Shuhei Yoshida. The address of Senju Pharmaceuticals Co., Ltd. is 2-5-8, Hirano-machi, Chuo-ku, Osaka, Japan.

(11) Includes 1,750,000 shares of common stock and 1,050,000 shares of common stock underlying options.

(12) Includes 1,700,000 shares of common stock underlying Series A preferred stock and 357,114 shares of common stock underlying Series B preferred stock.

(13) Includes 1,750,000 shares of common stock. Barry Butler is the CEO and managing member of PointGuard Partners, LLC and therefore, may be deemed to have beneficial ownership of the shares of common stock held by PointGuard Partners, LLC. The address of PointGuard Partners, LLC is 400 N. Ashley St., Suite 2150, Tampa, Florida 33602.

(14) Includes 607,848 shares of common stock, 608,349 shares of common stock underlying Series A preferred stock, 294,216 shares of common stock underlying Series A-2 preferred stock and 193,081 shares of common stock underlying Series B preferred stock. The address of John J. Mack is c/o Sunstreet Corp., 6 Club Rd., Rye New York 10580.

(15) Includes (i) 1,750,000 shares of common stock and 675,000 shares of common stock underlying options held by Barry Butler directly and (ii) 1,750,000 shares of common stock held by Point Guard Partners, LLC. Barry Butler is the CEO and managing member of PointGuard Partners, LLC and therefore, may be deemed to have beneficial ownership of the shares of common stock held by PointGuard Partners, LLC. The address of Barry Butler is 960 S Florida Avenue, Tarpin Springs, FL 34689.

(16) Includes 2,911,141 shares of common stock, 2,434,290 shares of common stock underlying options that are exercisable within 60 days of November 15, 2017, 9,224,503 shares of common stock underlying Series A preferred stock, 816,950 shares of common stock underlying Series A-2 preferred stock and 2,207,880 shares of common stock underlying Series B preferred stock.

DESCRIPTION OF SECURITIES

General

Our certificate of incorporation, as amended, authorizes the issuance of up to 60,000,000 shares of common stock, par value $0.0001 per share, and 36,000,000 shares of preferred stock, par value $0.0001 per share. The preferred stock has been designated as follows: 20,000,000 shares have been designated as Series A preferred stock, 5,714,286 shares have been designated as Series A-2 preferred stock and 10,000,000 shares have been designated as Series B preferred stock. As of September 30, 2017, we had 9,624,488 shares of common stock issued and outstanding, 10,996,614 shares of Series A preferred stock issued and outstanding, 2,958,100 shares of Series A-2 preferred stock issued and outstanding and 3,446,058 shares of Series B preferred stock issued and outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our Board of Directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Our certificate of incorporation, as amended, authorizes the issuance of 36,000,000 shares of blank check preferred stock with such designation, rights and preferences as may be determined from time to time by our Board of Directors. On October 9, 2014, we designated 20,000,000 shares of preferred stock as Series A preferred stock. On October 6, 2016, we designated 5,714,286 shares of preferred stock as Series A-2 preferred stock. In 2017, we designated 10,000,000 shares of preferred stock as Series B preferred stock. Accordingly, as of the date of this prospectus there are 285,714 shares of blank check preferred stock available for future designation. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. We may issue some or all of the preferred stock to effect a business transaction. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us.

Series A Preferred Stock

As of November 15, 2017, we had 10,996,614 shares of Series A preferred stock issued and outstanding. Each share of Series A preferred stock is convertible, at the option of the holder, into one share of common stock, subject to certain adjustments. In addition, each share of Series A preferred stock will automatically convert into one share of our common stock immediately prior to the closing of this offering, subject to certain adjustments. Series A preferred stock is not entitled to receive any annual dividend. In the event of a liquidation or dissolution of our Company, holders of Series A preferred stock are entitled to receive $1.00 per share pari passu with holders of Series A-2 preferred stock and in preference to holders of common stock.

Series A-2 Preferred Stock

As of November 15, 2017, we had 2,958,100 shares of Series A-2 preferred stock issued and outstanding. Each share of Series A-2 preferred stock is convertible, at the option of the holder, into one share of common stock, subject to certain adjustments. In addition, each share of Series A-2 preferred

stock will automatically convert into one share of our common stock immediately prior to the closing of this offering, subject to certain adjustments. Series A-2 preferred stock is not entitled to receive any annual dividend. In the event of a liquidation or dissolution of our Company, holders of Series A-2 preferred stock are entitled to receive $1.40 per share pari passu with holders of Series A preferred stock and in preference to holders of common stock.

Series B Preferred Stock

As of November 15, 2017, we had 3,446,058 shares of Series B preferred stock issued and outstanding. Each share of Series B preferred stock is convertible, at the option of the holder, into one share of common stock, subject to certain adjustments. In addition, each share of Series B preferred stock will automatically convert into one share of our common stock immediately prior to the closing of this offering, subject to certain adjustments. Series B preferred stock is entitled to receive dividend at an annual rate of $0.1488 per share in preference to any dividends payable to all other equity securities. The dividend preference of any Series B preferred stock may be waived, in whole or in part, by the consent or vote of the holders of at least seventy-five percent (75%) of the outstanding Series B preferred stock. In the event of a liquidation or dissolution of our Company, holders of Series B preferred stock are entitled to receive $1.86 per share in preference to holders of our other equity securities.

Options

As of November 15, 2017, options to purchase an aggregate of 6,466,534 shares of our common stock, at a weighted average exercise price of $0.45 per share, were outstanding.

Registration Rights

Demand Registration Rights

Pursuant to certain Investor's Rights Agreement, as amended, or Rights Agreement, between us and the holders of our Series A preferred stock, Series A-2 preferred stock and Series B preferred stock, beginning on the earlier of 10 year anniversary of the Rights Agreement or the 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of 8,700,387 shares of our common stock to be issued pursuant to conversion of all of our outstanding Series A preferred stock, Series A-2 preferred stock and Series B preferred stock, or Preferred Conversion Shares, or 1,723,030 shares of our common stock to be issued pursuant to conversion of Series B preferred stock, or Series B Conversion Shares, will be entitled to certain demand registration rights. At any time, the holders of more than 50% of the Preferred Conversion Shares and holders of more than 50% of the Series B Conversion Shares can each, on not more than two occasions, request that we register all or a portion of their shares. Such request for registration must cover that number of shares with an anticipated offering price of at least $2.00 per share or aggregate offering price of at least $20 million. Additionally, we will not be required to effect a demand registration during the period beginning 60 days prior to our good faith estimate of the date of filing and 180 days following the effectiveness of a company-initiated registration statement relating to a public offering of our securities.

Piggyback Registration Rights

After the completion of this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of approximately 17,400,772 shares of our common stock to be issued pursuant to conversion of our Series A preferred stock, Series A-2 preferred stock and Series B preferred stock, will be entitled to certain "piggyback" registration rights allowing such holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, debt securities or corporate reorganizations, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

Form S-3 Registration Rights

After the completion of this offering and beginning on the earlier of 10 year anniversary of the Rights Agreement or the 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of approximately _____ shares of our common stock issuable pursuant to conversion of our Series A preferred stock, Series A-2 preferred stock and Series B preferred stock will be entitled to certain Form S-3 registration rights. The holders of these shares can make a written request that we register their shares of common stock on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $1 million. These holders may make an unlimited number of requests for registration on Form S-3.

We will pay the registration expenses of the holders of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described above. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

The demand, piggyback and Form S-3 registration rights described above will expire upon the earlier of (i) three years after the completion of this offering, or (ii) with respect to any particular stockholder, the date on which such stockholder can sell all of its shares under Rule 144 of the Securities Act during any 90 day period.

Provisions of our Certificate of Incorporation and Bylaws, and Delaware Law that May Have an Anti-Takeover Effect

Certain provisions set forth in our certificate of incorporation, as amended, and bylaws and Delaware law could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management.

Certificate of Incorporation and Bylaws

In particular, our certificate of incorporation, as amended, and bylaws, among other things:

- provide that stockholders must provide advance notice to nominate persons for election to our Board of Directors or submit proposals for consideration at stockholder meetings;
- specify that special meetings of our stockholders can be called only by the chairman of the Board of Directors, the President or such other persons designated by the Board of Directors; and
- provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum, or by the sole remaining director.

Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, regulating corporate takeovers. In general, DGCL Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder: (i) shares owned by persons who are directors and also officers; and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our Board of Directors does not approve in advance. We also anticipate that DGCL Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Disclosure of Commission Position on Indemnification for Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be _____. The transfer agent's address is _____, and its telephone number is _____. Our shares of common stock will be issued in uncertificated form only, subject to limited circumstances.

Market Listing

We intend to apply to list our common stock on the NASDAQ Capital Market under the symbol "EYEN."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has not been a public market for shares of our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon the completion of this offering, assuming no exercise of the underwriters' option to purchase additional shares, shares of common stock will be outstanding assuming an initial public offering price of $ per share. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Of the remaining shares of common stock outstanding after this offering that were not sold in this offering (including shares issued upon conversion of Series A preferred stock, Series A-2 preferred stock and Series B preferred stock or exercise of options), approximately shares of common stock will be restricted as a result of securities laws or lock-up agreements (see "Lock-up Agreements" below) and approximately shares of common stock will be freely tradable. The approximately remaining shares will generally become available for sale in the public market as follows: and approximately restricted shares held by non-affiliates will be eligible for sale under Rule 144 or Rule 701 upon expiration of lock-up agreements at least 180 days after the date of this offering.

The remaining outstanding shares of our common stock will be deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, all of our security holders have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below. As a result of these agreements, subject to the provisions of Rule 144 or Rule 701, shares will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all of the shares sold in this offering will be immediately available for sale in the public market (except as described above); and
- beginning 181 days after the date of this prospectus, additional shares will become eligible for sale in the public market, of which shares will be held by affiliates and subject to the volume and other restrictions of Rule 144 and Rule 701 as described below.

Lock-Up Agreements

All of our directors and executive officers and all of our major stockholders are subject to lock-up agreements that, subject to certain exceptions, prohibit them from directly or indirectly offering, pledging, selling, contracting to sell, selling any option or contract to purchase, purchasing any option or contract to purchase, granting any option, right or warrant to purchase or otherwise transferring or disposing of any shares of our common stock, options to acquire shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock, whether now owned or hereafter acquired, or entering into any swap or any other agreement or any transaction that transfer, in whole or in part, directly or indirectly, the economic consequence of ownership, for a period of 180 days following the date of this prospectus, without the prior written consent of Ladenburg Thalmann & Co. Inc. These agreements are described in the section entitled "Underwriting."

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information

requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described above, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701 and are subject to the lock-up agreements described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a summary of the material U.S. federal income tax consequences applicable to non-U.S. holders (as defined below) with respect to the acquisition, ownership and disposition of shares of our common stock, but does not purport to be a complete analysis of all potential tax considerations related thereto. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended, or the Code, final, temporary or proposed Treasury regulations promulgated thereunder, administrative rulings and judicial opinions, all of which are subject to change, possibly with retroactive effect. We have not sought any ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This summary is limited to non-U.S. holders who purchase shares of our common stock issued pursuant to this offering and who hold such shares of our common stock as capital assets (within the meaning of Section 1221 of the Code).

This discussion does not address all aspects of U.S. federal income taxation that may be important to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address the potential application of the Medicare contribution tax, any aspects of U.S. federal estate or gift tax laws, or tax considerations arising under the laws of any non-U.S., state or local jurisdiction. This discussion also does not address tax considerations applicable to a non-U.S. holder subject to special treatment under the U.S. federal income tax laws, including without limitation:

- banks, insurance companies or other financial institutions;
- partnerships or other pass-through entities;
- tax-exempt organizations;
- tax-qualified retirement plans;
- dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- U.S. expatriates and certain former citizens or long-term residents of the U.S.;
- controlled foreign corporations;
- passive foreign investment companies;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock; and
- persons that will hold common stock as a position in a hedging transaction, "straddle" or "conversion transaction" for tax purposes.

If a partnership (or entity classified as a partnership for U.S. federal income tax purposes) is a beneficial owner of shares of our common stock, the tax treatment of a partner in the partnership (or member in such other entity) will generally depend upon the status of the partner and the activities of the partnership. Any partner in a partnership holding shares of our common stock (and such partnership) should consult their own tax advisors.

PROSPECTIVE INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF SHARES OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S. OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this summary, a "non-U.S. holder" is any beneficial owner of shares of our common stock (other than a partnership or other entity treated as a partnership for U.S. federal income tax purposes) that is not a U.S. person. A "U.S. person" is any of the following:

- an individual citizen or resident of the U.S.;
- a corporation created or organized in or under the laws of the U.S., any state thereof or the District of Columbia (or any other entity treated as such for U.S. federal income tax purposes);
- an estate, the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if: (i) a court within the U.S. is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust; or (ii) it has a valid election in effect under applicable Treasury regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in the section titled "Dividend Policy," we currently do not anticipate paying dividends on our common stock in the foreseeable future. If, however, we make cash or other property distributions on our common stock (other than certain pro rata distributions of shares of our common stock), such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current earnings and profits for that taxable year or our accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's adjusted tax basis in the shares of our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of shares of our common stock and will be treated as described under the section titled "— Gain on Sale or Other Disposition of Shares of Our Common Stock" below.

Dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN or W-8BEN-E (or other applicable form) certifying, under penalties of perjury, such holder's qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically.

If a non-U.S. holder holds shares of our common stock in connection with the conduct of a trade or business in the U.S., and dividends paid on shares of our common stock are effectively connected with such holder's U.S. trade or business (and, if required by an applicable income tax treaty, are attributable to a permanent establishment maintained by the non-U.S. holder in the U.S.), the non-U.S. holder will be exempt from the aforementioned U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI (or other applicable form).

Such effectively connected dividends generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the U.S. A non-U.S. holder that is a non-U.S. corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year. Non-U.S. holders should consult any applicable income tax treaties that may provide for different rules.

A non-U.S. holder that claims exemption from withholding or the benefit of an applicable income tax treaty generally will be required to satisfy applicable certification and other requirements prior to the distribution date. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty or applicability of other exemptions from withholding.

Gain on Sale or Other Disposition of Shares of Our Common Stock

Subject to the discussion below regarding backup withholding and the Foreign Account Tax Compliance Act, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of shares of our common stock unless:

- the gain is effectively connected with a trade or business carried on by the non-U.S. holder in the U.S. and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment of the non-U.S. holder maintained in the U.S.;
- the non-U.S. holder is an individual present in the U.S. for 183 days or more in the taxable year of disposition and certain other requirements are met; or
- we are or have been a U.S. real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period for the shares of our common stock, and our common stock has ceased to be traded on an established securities market prior to the beginning of the calendar year in which the sale or other disposition occurs. The determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests.

We believe we currently are not, and we do not anticipate becoming, a USRPHC for U.S. federal income tax purposes.

Gain described in the first bullet point above will be subject to U.S. federal income tax on a net income basis at regular graduated U.S. federal income tax rates generally in the same manner as if such holder were a resident of the U.S. A non-U.S. holder that is a non-U.S. corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year. Non-U.S. holders should consult any applicable income tax treaties that may provide for different rules.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty) but may be offset by U.S. source capital losses (even though the individual is not considered a resident of the U.S.), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S.holders should consult any applicable income tax treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S.holder resides or is established. Backup withholding, currently at a 28% rate, generally will not apply to distributions to a non-U.S. holder of shares of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification as to its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that the holder is a U.S. person that is not an exempt recipient.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Foreign Account Tax Compliance Act

Legislation and administrative guidance, commonly referred to as "FATCA", may impose a 30% withholding tax on any dividends paid after July 1, 2014 and the proceeds of a sale of our common stock paid after December 31, 2018 to a "foreign financial institution", as specially defined under such rules, and certain other foreign entities, unless various information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in, or accounts with, those entities) have been

met or an exemption applies. If FATCA withholding is imposed, a beneficial owner that is not a foreign financial institution generally will be entitled to a refund of any amounts withheld by filing a U.S. federal income tax return (which may entail significant administrative burden). Prospective investors should consult their tax advisors regarding FATCA.

UNDERWRITING

We have entered into an underwriting agreement dated _____, 2017, with Ladenburg Thalmann & Co. Inc. and Roth Capital Partners, LLC, acting as representatives of the underwriters and joint book-running managers of this offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

Underwriter	Number of shares
Ladenburg Thalmann & Co. Inc.	
Roth Capital Partners, LLC	_____
Total	_____

We have been advised by the underwriters that they proposes to offer the shares directly to the public at the public offering price set forth on the cover page of this prospectus. Any shares sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of per share. The underwriters may allow, and these selected dealers may re-allow, a concession of not more than _____ per share to other brokers and dealers.

The underwriting agreement provides that the underwriters' obligation to purchase the shares we are offering is subject to the terms and conditions described therein.

No action has been taken by us or the underwriters that would permit a public offering of the shares in any jurisdiction where action for that purpose is required. None of our shares included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the shares offered hereby be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of shares and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the shares in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

Over-Allotment Option

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to _____ additional shares from us at the public offering price set forth on the cover page of this prospectus, less the underwriting discount and commission. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares offered by this prospectus.

Underwriting Discount and Expenses

The following table shows the public offering price, underwriting discount and commission, and proceeds before expenses to us. The information assumes either no exercise or full exercise of the option we granted to the underwriters to purchase additional shares.

		Total	
	Per share	No exercise	Full exercise
Public offering price	$	$	$
Underwriting discounts and commissions			
Proceeds, before expenses, to us			

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $_____. We have agreed to reimburse the underwriters for expenses relating to this offering of up to $_____.

Determination of Offering Price

Prior to the completion of this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the underwriters. Among the factors considered in determining the initial public offering price will be the history and prospects of other companies in the industry in which we compete; our financial information; an assessment of our management and their experience; an assessment of our business potential and earning prospects; the prevailing securities markets at the time of this offering; the recent market prices of, and the demand for, publicly traded shares of generally comparable companies; and other factors deemed relevant. Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Lock-up Agreements

We and all of our officers and directors and all of our major stockholders have agreed, that for a period of 180 days after the date of this prospectus, or the lock-up period, subject to certain limited exceptions described below, we and they will not directly or indirectly, without the prior written consent of the underwriters offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 180 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing equity incentive plans. The underwriters may, in their sole discretion and without notice, waive the terms of any of these lock-up agreements.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions and syndicate covering transactions and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Since there is no over-allotment option, if the underwriters would have a naked short position, it can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the security originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions. These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters makes any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Indemnification

We have agreed to indemnify the underwriters and selected dealers against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriter or selected dealers may be required to make for these liabilities.

Listing on the NASDAQ Capital Market

We intend to apply to list our common stock on the NASDAQ Capital Market under the symbol "EYEN."

Electronic Distribution

A prospectus in electronic format may be made available on websites maintained by the underwriters, or selling group members, if any, participating in this offering. The underwriters may agree to allocate a number of shares of our common stock for sale to its online brokerage account holders.

Other Relationships

The underwriters and their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing, and brokerage activities. The underwriters and their affiliates may in the future perform various financial advisory, investment banking, and other services for us, for which they may receive customary fees and commissions. In addition, in the ordinary course of their various business activities, the underwriters and their affiliates may effect transactions for their own account or the accounts of customers, and hold on behalf of themselves or their customers long or short positions in our debt or equity securities or loans, and may do so in the future. The underwriters and their affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to their customers that they acquire, long or short positions in such securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area that has implemented the Prospectus Directive (each a Relevant Member State), an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or the underwriters of a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision: (i) the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State; (ii) the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State; and (iii) the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

The underwriters have represented and agreed that:

- they only communicated or caused to be communicated, and will only communicate or cause to be communicated, an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (FSMA)) received by them in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

- they have complied and will comply with all applicable provisions of the FSMA with respect to anything done by them in relation to the shares of our common stock in, from, or otherwise involving the United Kingdom.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. The underwriters are being represented by Goodwin Procter LLP, New York, New York, in connection with this offering.

EXPERTS

Our financial statements as of and for the years ended December 31, 2016 and 2015 included in this prospectus have been audited by Marcum, LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance on such report given upon the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates or view them online. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements, and other information about us, are available at the SEC's website, *www.sec.gov*.

As a result of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *http://www.eyenoviabio.com/*. Upon the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

EYENOVIA, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Eyenovia, Inc.

We have audited the accompanying balance sheets of Eyenovia, Inc. (the "Company") as of December 31, 2016 and 2015, and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Eyenovia, Inc. as of December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP

Marcum LLP
New York, NY
November 15, 2017

EYENOVIA, INC.

Balance Sheets

	December 31,	
	2016	**2015**
Assets		
Current Assets:		
Cash	$ 3,387,288	$ 2,492,611
Prepaid expenses and other current assets	2,335	312,833
Total Current Assets	3,389,623	2,805,444
Property and equipment, net	43,192	12,875
Total Assets	$ 3,432,815	$ 2,818,319
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 302,031	$ 246,522
Accrued expenses and other current liabilities	121,703	173,301
Total Current Liabilities	423,734	419,823
Commitments and contingencies (Note 7)	—	—
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 36,000,000 shares authorized;		
Series A Convertible Preferred Stock, 20,000,000 shares designated, 12,121,102 shares issued and outstanding as of December 31, 2016 and 2015, liquidation preference of $12,121,102 as of December 31, 2016 and 2015	1,212	1,212
Series A-2 Convertible Preferred Stock, 5,714,286 shares designated, 2,958,100 and 0 shares issued and outstanding as of December 31, 2016 and 2015, respectively, liquidation preference of $4,141,338 and $0 as of December 31, 2016 and 2015, respectively	296	—
Series B Convertible Preferred Stock, 10,000,000 shares designated, 0 shares issued and outstanding as of December 31, 2016 and 2015, liquidation preference of $0 as of December 31, 2016 and 2015	—	—
Common stock, $0.0001 par value, 60,000,000 shares authorized; 8,500,000 shares issued and outstanding as of December 31, 2016 and 2015	850	850
Additional paid-in capital	17,137,922	12,994,190
Accumulated deficit	(14,131,199)	(10,597,756)
Total Stockholders' Equity	3,009,081	2,398,496
Total Liabilities and Stockholders' Equity	$ 3,432,815	$ 2,818,319

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Operations

	For the Years Ended, December 31,	
	2016	**2015**
Operating Expenses:		
Research and development	$ 2,966,165	$ 2,783,200
General and administrative	568,775	1,486,401
Total Operating Expenses	3,534,940	4,269,601
Loss From Operations	(3,534,940)	(4,269,601)
Other Income:		
Interest income	1,497	2,412
Total Other Income	1,497	2,412
Net Loss	$(3,533,443)	$(4,267,189)
Net Loss Per Share–Basic and Diluted	$ (0.42)	$ (0.50)
Weighted Average Number of Common Shares Outstanding–Basic and Diluted	8,500,000	8,500,000

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2016 and 2015

	Convertible Preferred Stock								
	Series A		Series A-2		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance–January 1, 2015	7,121,102	$ 712	—	$ —	8,500,000	$850	$ 7,120,890	$ (6,330,567)	$ 791,885
Issuance of Series A convertible preferred stock	5,000,000	500	—	—	—	—	4,999,500	—	5,000,000
Stock-based compensation	—	—	—	—	—	—	873,800	—	873,800
Net loss	—	—	—	—	—	—	—	(4,267,189)	(4,267,189)
Balance–December 31, 2015	12,121,102	$1,212	—	—	8,500,000	$850	$12,994,190	$(10,597,756)	$ 2,398,496
Issuance of Series A-2 convertible preferred stock	—	—	2,958,100	296	—	—	4,141,042	—	4,141,338
Stock-based compensation	—	—	—	—	—	—	2,690	—	2,690
Net loss	—	—	—	—	—	—	—	(3,533,443)	(3,533,443)
Balance–December 31, 2016	12,121,102	$1,212	2,958,100	$296	8,500,000	$850	$17,137,922	$(14,131,199)	$ 3,009,081

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Cash Flows

	For the Years Ended December 31,	
	2016	**2015**
Cash Flows From Operating Activities		
Net loss	$(3,533,443)	$(4,267,189)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	12,802	9,698
Gain on sale of property and equipment	—	(2,702)
Stock-based compensation	2,690	873,800
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	310,498	(312,833)
Accounts payable	55,509	84,135
Accrued expenses and other current liabilities	(51,598)	(216,055)
Net Cash Used In Operating Activities	(3,203,542)	(3,831,146)
Cash Flows From Investing Activities		
Sale of property and equipment	—	4,790
Purchases of property and equipment	(43,119)	(4,967)
Net Cash Used In Investing Activities	(43,119)	(177)
Cash Flows From Financing Activities		
Proceeds from sale of Series A Convertible Preferred Stock	—	5,000,000
Proceeds from sale of Series A-2 Convertible Preferred Stock	4,141,338	—
Net Cash Provided By Financing Activities	4,141,338	5,000,000
Net Increase in Cash	894,677	1,168,677
Cash–Beginning of Year	2,492,611	1,323,934
Cash–End of Year	$ 3,387,288	$ 2,492,611
Supplemental Disclosures of Cash Flow Information:		
Cash Paid During the Periods For:		
Interest	$ —	$ —
Income taxes	$ —	$ —

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 1 — Business Organization and Nature of Operations

Eyenovia, Inc. ("Eyenovia" or the "Company") was organized as a corporation under the laws of the State of Florida on March 12, 2014 under the name, PGP Holdings V, Inc. On May 5, 2014, PGP Holdings V, Inc. changed its name to Eyenovia, Inc. On October 6, 2014, Eyenovia, Inc. reincorporated in the State of Delaware by merging into Eyenovia, Inc., a Delaware corporation.

Eyenovia is a clinical stage biopharmaceutical company developing a pipeline of ophthalmology products utilizing its patented piezo-print technology to deliver micro-doses (6–8 μL) of active pharmaceutical ingredients (or "micro-therapeutics") topically to the eye. This disruptive micro-dosing technology has the potential to replace traditional macro-dosing applications (e.g. conventional eye droppers), that routinely overdoses or under-doses the topical administration of ophthalmic therapeutics.

In appropriate circumstances, Eyenovia intends to use the regulatory pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which enables a potentially shorter development timeline for its product candidates by allowing it to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. Eyenovia has received written FDA feedback indicating that it can proceed to Phase III clinical trials for two of its lead programs: MicroProst, a novel micro-therapeutic latanoprost formulation for chronic angle closure glaucoma ("CACG"), an indication with no FDA-approved drug treatments; and MicroStat, a fixed combination of micro-therapeutic phenylephrine-tropicamide formulation for mydriasis, also known as pupil dilation for use in eye exams. MicroTears, its over-the-counter ("OTC") treatment for dry eye will not require Phase III studies, and Eyenovia plans to proceed with registration activities.

On October 10, 2014, Eyenovia entered into an asset purchase agreement and plan of reorganization with Corinthian Ophthalmic, Inc. ("Corinthian") (the "Asset Purchase Agreement"). Pursuant to the Asset Purchase Agreement, Corinthian agreed to sell its intellectual property portfolio and related assets to Eyenovia for an aggregate of 5,000,000 shares of common stock of Eyenovia. In addition, Corinthian's noteholders received an aggregate of 5,421,102 shares of Series A Convertible Preferred Stock of Eyenovia in satisfaction of notes payable with an aggregate principal balance of $5,421,102. See Note 9 — Stockholders' Equity for additional details. As a result of the high degree of common ownership between the parties, the transaction was deemed to lack economic substance and, as a result, was recorded at historical carry-over basis.

Note 2 — Summary of Significant Accounting Policies

Liquidity and Financial Condition

The Company incurred net losses of $3,533,443 and $4,267,189 for the years ended December 31, 2016 and 2015, respectively. At December 31, 2016, the Company's working capital and accumulated deficit were $2,965,889 and $14,131,199, respectively. The Company has not yet generated revenues or achieved profitability and it is expected that its research and development and general and administrative expenses will continue to increase and, as a result, the Company will eventually need to generate significant product revenues to achieve profitability. Subsequent to December 31, 2016, the Company raised aggregate net proceeds of $6,809,988 in connection with a Series B Convertible Preferred Stock purchase agreement. See Note 10 — Subsequent Events for additional details.

The Company believes its current cash on hand is sufficient to meet its operating and capital requirements for at least the next twelve months from the date of the issuance of this report. Thereafter, the Company will need to raise further capital, through the sale of additional equity or debt securities, to support its future operations. The Company's operating needs include the planned costs to operate its business, including amounts required to fund working capital and capital expenditures. The Company's future capital requirements and the adequacy of its available funds will depend on many factors, including the Company's ability to successfully commercialize its products and services, competing technological and

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 2 — Summary of Significant Accounting Policies (continued)

market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings.
If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash.

Use of Estimates

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and the amounts disclosed in the related notes to the financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, fair value calculations for equity securities, establishing valuation allowances for deferred tax assets, stock-based compensation, the recoverability and useful lives of long-lived assets and the recovery of deferred costs. Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates.

Cash

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents in the financial statements. As of December 31, 2016 and 2015, the Company had no cash equivalents.

The Company has cash on deposits in several financial institutions which, at times, may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions. As of December 31, 2016 and 2015, the Company had cash balances in excess of FDIC insurance limits of $3,137,288 and $2,242,611, respectively.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation, which is recorded commencing at the in-service date using the straight-line method at rates sufficient to charge the cost of depreciable assets to operations over their estimated useful lives, which range from 2 to 5 years. Leasehold improvements are amortized over the lesser of (a) the useful life of the asset; or (b) the remaining lease term. Maintenance and repairs are charged to operations as incurred. The Company capitalizes costs attributable to the betterment of property and equipment when such betterment extends the useful life of the assets.

Intangible Assets

Intangible assets subject to amortization are capitalized and amortized over their estimated useful lives on a straight-line basis.

Impairment of Long-lived Assets

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 2 — Summary of Significant Accounting Policies (continued)

eventual disposition are less than its carrying amount. The Company has not recorded any impairment losses at December 31, 2016 and 2015.

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Convertible Instruments

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Topic 815 of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). The accounting treatment of derivative financial instruments requires that the Company record embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Embedded conversion options and any related freestanding instruments are recorded as a discount to the host instrument.

If the instrument is determined to a derivative liability, the Company then evaluates for the existence of a beneficial conversion feature by comparing the market price of the Company's common stock as of the commitment date to the effective conversion price of the instrument.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of ASC 820 "Fair Value Measurements and Disclosures" ("ASC 820") which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The carrying amounts of the Company's financial instruments, such as cash, accounts payable, accrued expenses and other current liabilities approximate fair values due to the short-term nature of these instruments.

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 2 — Summary of Significant Accounting Policies (continued)

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

The Company utilizes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements as of December 31, 2016 and 2015. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the statements of operations.

Research and Development

Research and development expenses are charged to operations as incurred. The Company records prepaid expenses on its balance sheet for the payment of research and development expenses in advance of services being provided.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. The fair value of the Company's equity instruments was estimated by management based on observations of the cash sales prices of the Company's convertible preferred stock. Awards granted to directors are treated on the same basis as awards granted to employees. Upon the exercise of an option, the Company issues new shares of common stock out of its authorized shares.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	December 31,	
	2016	2015
Options	2,950,000	2,850,000
Series A Convertible Preferred Stock	12,121,102	12,121,102
Series A-2 Convertible Preferred Stock	2,958,100	—
Total potentially dilutive shares	18,029,202	14,971,102

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 2 — Summary of Significant Accounting Policies (continued)

Subsequent Events

The Company has evaluated subsequent events through the date which the financial statements were available to be issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers," ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC 605 — Revenue Recognition ("ASC 605") and most industry-specific guidance throughout ASC 605. The standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The guidance in ASU 2014-09 was revised in July 2015 to be effective for interim periods beginning on or after December 15, 2017 and should be applied on a transitional basis either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. In 2016, FASB issued additional ASUs that clarify the implementation guidance on principal versus agent considerations (ASU 2016-08), on identifying performance obligations and licensing (ASU 2016-10), and on narrow-scope improvements and practical expedients (ASU 2016-12) as well as on the revenue recognition criteria and other technical corrections (ASU 2016-20). Since the Company has not generated any revenue since its inception, it does not anticipate that the adoption of these ASUs will have a material impact on its financial position, results of operations, and cash flows.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," ("ASU 2014-15"). ASU 2014-15 explicitly requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist which raise substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and annual and interim periods thereafter, with early adoption permitted. The Company adopted this standard effective January 1, 2015 and its adoption did not have a material impact on its financial position, results of operations, and cash flows.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes," ("ASU 2015-17"). The FASB issued ASU 2015-17 as part of its ongoing Simplification Initiative, with the objective of reducing complexity in accounting standards. The amendments in ASU 2015-17 require entities that present a classified balance sheet to classify all deferred tax liabilities and assets as a noncurrent amount. This guidance does not change the offsetting requirements for deferred tax liabilities and assets, which results in the presentation of one amount on the balance sheet. Additionally, the amendments in ASU 2015-17 align the deferred income tax presentation with the requirements in International Accounting Standards (IAS) 1, Presentation of Financial Statements. The amendments in ASU 2015-17 are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company does not anticipate that the adoption of this standard will have a material impact on its financial position, results of operations, and cash flows.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," ("ASU 2016-02"). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 2 — Summary of Significant Accounting Policies (continued)

investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating ASU 2016-02 and its impact on its financial position, results of operations, and cash flows.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation — Stock Compensation (Topic 718)," ("ASU 2016-09"). ASU 2016-09 requires an entity to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating ASU 2016-09 and its impact on its financial position, results of operations, and cash flows.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments," ("ASU 2016-15"). The new standard will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017. We will require adoption on a retrospective basis unless it is impracticable to apply, in which case we would be required to apply the amendments prospectively as of the earliest date practicable. The Company is currently evaluating ASU 2016-15 and its impact on its financial position, results of operations, and cash flows.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting," ("ASU 2017-09"). ASU 2017-09 provides clarity on the accounting for modifications of stock-based awards. ASU 2017-09 requires adoption on a prospective basis in the annual and interim periods for our fiscal year ending December 15, 2017 for share-based payment awards modified on or after the adoption date. The Company is currently evaluating ASU 2017-09 and its impact on its financial position, results of operations, and cash flows.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260) and Derivatives and Hedging (Topic 815) — Accounting for Certain Financial Instruments with Down Round Features," ("ASU 2017-11"). Equity-linked instruments, such as warrants and convertible instruments may contain down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. Under ASU 2017-11, a down round feature will no longer require a freestanding equity-linked instrument (or embedded conversion option) to be classified as a liability that is remeasured at fair value through the income statement (i.e. marked-to-market). However, other features of the equity-linked instrument (or embedded conversion option) must still be evaluated to determine whether liability or equity classification is appropriate. Equity classified instruments are not marked-to-market. For earnings per share ("EPS") reporting, the ASU requires companies to recognize the effect of the down round feature only when it is triggered by treating it as a dividend and as a reduction of income available to common shareholders in basic EPS. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in any interim period. The Company is currently evaluating ASU 2017-11 and its impact on its financial position, results of operations, and cash flows.

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 3 — Prepaid Expenses and Other Current Assets

As of December 31, 2016 and 2015, prepaid expenses and other current assets consisted of the following:

	December 31,	
	2016	2015
Prepaid research and development expenses	$ —	$310,755
Prepaid insurance expenses	2,335	2,078
Total prepaid expenses and other current assets	$2,335	$312,833

Note 4 — Property and Equipment, Net

As of December 31, 2016 and 2015, property and equipment consisted of the following:

	December 31,	
	2016	2015
Equipment	$ 24,745	$21,626
Leasehold improvements	40,000	—
	64,745	21,626
Less: accumulated depreciation and amortization	(21,553)	(8,751)
Property and equipment, net	$ 43,192	$12,875

Depreciation and amortization expense was $12,802 and $9,698 for the years ended December 31, 2016 and 2015, respectively, which is included within research and development expenses in the statements of operations.

Note 5 — Accrued Expenses and Other Current Liabilities

As of December 31, 2016, and 2015, accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2016	2015
Accrued research and development expenses	$ 61,000	$131,395
Accrued legal expenses	37,597	26,025
Accrued rent expense	18,590	—
Other	4,516	15,881
Total accrued expenses and other current liabilities	$121,703	$173,301

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 6 — Income Taxes

The income tax (provision) benefit consists of the following:

	For The Years Ended December 31,	
	2016	2015
Federal:		
Current	$ —	$ —
Deferred	1,287,931	1,542,279
State and local:		
Current	—	—
Deferred	151,521	181,444
	1,439,452	1,723,723
Change in valuation allowance	(1,439,452)	(1,723,723)
Income tax (provision) benefit	$ —	$ —

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	For The Years Ended December 31,	
	2016	2015
Tax benefit at federal statutory rate	34.0%	34.0%
State income taxes, net of federal benefit	4.0%	4.0%
Incremental research and development credits	2.7%	2.4%
Change in valuation allowance	(40.7)%	(40.4)%
Effective income tax rate	0.0%	0.0%

The tax effects of temporary differences that give rise to deferred tax assets and liabilities are presented below:

	December 31,	
	2016	2015
Deferred Tax Assets:		
Net operating loss carryforwards	$ 2,742,397	$ 1,383,364
Stock-based compensation	333,066	332,044
Research & development tax credits	201,840	105,096
Intangible assets	234,183	251,530
Gross deferred tax assets	3,511,486	2,072,034
Valuation allowance	(3,511,486)	(2,072,034)
Deferred tax asset, net of valuation allowance	$ —	$ —
Changes in valuation allowance	$(1,439,452)	$(1,723,723)

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 6 — Income Taxes (continued)

The Company assesses the likelihood that deferred tax assets will be realized. To the extent that realization is not likely, a valuation allowance is established. Based upon the Company's history of losses since inception, management believes that it is more likely than not that future benefits of deferred tax assets will not be realized.

At December 31, 2016 and 2015, the Company had approximately $7,200,000 and $3,600,000, respectively, of federal net operating losses that may be available to offset future taxable income. State net operating losses are not materially different from the federal net operating losses. The net operating loss carry forwards, if not utilized, will expire from 2034 to 2036 for federal purposes. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carry forwards could become subject to annual limitations if there are greater than 50% ownership changes.

The Company files income tax returns in the U.S. federal jurisdiction and the state of Nevada (also formerly Florida), which remain subject to examination by the various taxing authorities beginning with the tax year ended December 31, 2014.

Note 7 — Commitments and Contingencies

Operating Leases

On September 15, 2016, the Company entered into a lease agreement to lease 953 square feet of space located in Reno, NV with respect to its research and development activities. The monthly base rent is $3,895 per month over the term of the lease. The lease expires on September 14, 2018 and is subject to an extension at the option of the Company at a fixed rental rate for an additional 2-year period. The Company's rent expense amounted to $18,590 for the year ended December 31, 2016.

Future minimum payments under this operating lease agreement are as follows:

For the Years Ended December 31,	Amount
2017	$46,740
2018	33,108
	$79,848

Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

The Company, its Chief Executive Officer and members of its Board of Directors are named as defendants in a legal proceeding filed in the United States District Court for the District of New Jersey on September 2, 2014 that has not yet been fully resolved in connection with the Company's Asset Purchase Agreement with Corinthian. A shareholder of Corinthian, alleging a fraudulent transfer, is seeking to recover the purchase price of its Corinthian shares and other damages in aggregate amount of approximately $1.1 million. A settlement conference was conducted on July 24, 2017, however, the parties are not close to agreement on a settlement. On October 10, 2017, the Court denied each party's motion for summary judgment. The Company has filed a motion for reconsideration of the Court's decision, with particular focus on the dismissal of the claim against the Company. The motion for reconsideration will be heard on November 20, 2017. A pretrial conference is scheduled with the Court for December 18, 2017. The Company is indemnified by Corinthian and Corinthian's applicable insurance policy provides coverage of $10 million, such that the Company does not expect to incur a material loss as a result of this litigation and, as a result, did not record a loss contingency as of December 31, 2016 or 2015.

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 7 — Commitments and Contingencies (continued)

License Agreement

On March 18, 2015, the Company entered into a license agreement with Senju Pharmaceutical Co., Lt. ("Senju") (the "License Agreement") whereby the Company agreed to grant to Senju an exclusive, royalty-bearing license for its micro-dose product candidates for Asia to sublicense, develop, make, have made, manufacture, use, import, market, sell, and otherwise distribute the micro-dose product candidates. In consideration for the license, Senju agreed to pay to Eyenovia five percent (5%) royalties for the term of the license agreement. The agreement shall continue in full force and effect, on a country-by-country basis, until the latest to occur of: (i) the tenth (10th) anniversary of the first commercial sale of a micro-dose product candidate in Asia; or (ii) the expiration of the licensed patents in July 2031. As of the date of filing, there had been no commercial sales of a micro-dose product candidate in Asia such that no royalties had been earned. See Note 9 — Stockholders' Equity — Preferred Stock for details of the sale of Series A Convertible Preferred Stock to Senju.

Note 8 — Related Party Transactions

The Company's Chief Executive Officer as well as a member of its Board of Directors are both partners in Private Medical Equity, Inc. ("PME"). The Company and PME are parties to a consulting agreement dated November 4, 2014 that provides for the payment of $33,200 per month to PME in consulting fees for general management and strategy services. During the years ended December 31, 2016 and 2015, the Company incurred $398,400 and $398,400, respectively, related to the agreement, of which, $318,720 and $318,720, respectively, was included within research and development expenses and $79,680 and $79,680, respectively, was included within general and administrative expenses on the statements of operations.

A company that beneficially owns greater than 5% of the Company's common stock has a consulting agreement with the Company for research and development services. During the years ended December 31, 2016 and 2015, the Company recognized $366,209 and $407,613, respectively, related to the agreement, which was included within research and development expenses on the statements of operations.

Since July 2016, the Company pays $3,000 per month to a company controlled by a member of its Board of Directors for office space in New York, New York for its Chief Executive Officer. During the years ended December 31, 2016 and 2015, the Company recorded rent expense of $18,000 and $0, respectively, related to the office space.

Note 9 — Stockholders' Equity

Authorized Capital

The Company is authorized to issue 60,000,000 shares of common stock, par value of $0.0001 per share, and 36,000,000 shares of preferred stock, par value of $0.0001 per share. The holders of the Company's common stock are entitled to one vote per share. The preferred stock is designated as follows: 20,000,000 shares designated as Series A Convertible Preferred Stock; 5,714,286 shares designated as Series A-2 Convertible Preferred Stock; and 10,000,000 shares designated as Series B Convertible Preferred Stock.

2014 Equity Incentive Plan

The Company's 2014 Equity Incentive Plan ("2014 Plan") provides for the issuance of incentive stock options, nonstatutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock and restricted stock units to employees, directors and consultants of the Company and its affiliates. The common stock that may be issued pursuant to awards shall not exceed 3,500,000 shares in the

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 9 — Stockholders' Equity (continued)

aggregate. The 2014 Plan became effective on December 14, 2014 and shall terminate on the tenth (10th) anniversary of the effective date. In August 2016, the Company's Board of Directors and shareholders approved an amendment to the 2014 Plan to increase the number of shares of common stock authorized under the 2014 Plan from 3,500,000 shares to 6,500,000 shares. The 2014 Plan requires the exercise price of stock options to be greater than or equal to the fair value of the Company's common stock on the date of grant. As of December 31, 2016, there were 3,550,000 shares available for future issuance under the 2014 Plan.

Preferred Stock

On March 18, 2015, the Company sold an aggregate of 5,000,000 shares of Series A Convertible Preferred Stock to Senju at a price of $1.00 per share for aggregate proceeds of $5,000,000. See Note 7 — Commitments and Contingencies — License Agreement for details related to the License Agreement with Senju.

On October 6, 2016, the Company sold an aggregate of 2,958,100 shares of Series A-2 Convertible Preferred Stock to investors at a price of $1.40 per share for aggregate proceeds of $4,141,338.

The Series A and Series A-2 Convertible Preferred Stock is convertible, at the option of the holder, at any time into shares of common stock on a one-for-one basis. In the event of any issuances by the Company for less than the in-force conversion price, the preferred stock conversion price shall be reduced on a weighted average basis. Each share of preferred stock shall automatically be converted into shares of common stock at the then effective conversion price: (i) immediately prior to the closing of a firm commitment underwritten initial public offering provided that (A) the aggregate offering price, net of underwriters' discounts and expenses, is at least $2.00 per share of common stock and (B) the aggregate proceeds of such offering are not less than $30,000,000; or (ii) the date specified by written consent or agreement of the holders of at least 75% of the then outstanding shares of preferred stock. Subsequent to December 31, 2016, the $30,000,000 threshold discussed above was reduced to $20,000,000. See Note 10 — Subsequent Events — Series B Convertible Preferred Stock

In the event of the Company's liquidation, dissolution, or winding up, holders of preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount per share for each share of preferred stock held by them equal to the sum of (i) the liquidation preference specified for such share of preferred stock and (ii) all declared but unpaid dividends (if any) on such share of preferred stock. Dividends may be declared and paid on preferred stock when, and if, declared by the Board of Directors, out of any assets legally available. As of December 31, 2016, no dividends have been declared.

Except as otherwise required by law, the holders of shares of preferred stock shall vote on an as-if-converted-to-common-stock basis with the common stock.

The preferred stock does not contain a redemption provision and an overall analysis of its features performed by the Company determined that it is more akin to equity and therefore, has been classified within stockholders' equity on the balance sheet. While the embedded conversion option ("ECO") is subject to an anti-dilution price adjustment, since the ECO is clearly and closely related to the equity host, it is not required to be bifurcated and accounted for as a derivative liability under ASC 815. The Company determined that the preferred stock did not contain a beneficial conversion feature, since the conversion price exceeded the estimated fair value of the Company's common stock as of the commitment date.

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 9 — Stockholders' Equity (continued)

Stock Options

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following assumptions:

	For the Year Ended December 31,	
	2016	2015
Expected term (years)	10.00	5.00–10.00
Risk free interest rate	1.53%–1.83%	1.41%–1.93%
Expected volatility	131%	136%
Expected dividends	0.00%	0.00%

The Company has computed the fair value of options granted using the Black-Scholes option pricing model. Option forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate will be adjusted periodically based on the extent to which actual option forfeitures differ, or are expected to differ, from the previous estimate, when it is material. The Company estimated forfeitures related to option grants at an annual rate 0% for options granted during the years ended December 31, 2016 and 2015. The expected term used for options issued to non-employees is the contractual life and the expected term used for options issued to employees and directors is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" employee option grants. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S.Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

The weighted average estimated grant date fair value of the stock options granted during the years ended December 31, 2016 and 2015 was approximately $0.31 and $0.41 per share, respectively.

The Company recorded stock-based compensation expense related to stock options of $2,690 and $873,800 during the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, there was $41,032 of unrecognized stock-based compensation expense which will be recognized over a weighted average period of 2.8 years.

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 9 — Stockholders' Equity (continued)

A summary of the option activity during the year ended December 31, 2016 and 2015 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Oustanding January 1, 2015	—	$ —		
Granted	2,850,000	0.33		
Forfeited	—	—		
Oustanding December 31, 2015	2,850,000	0.33		
Granted	100,000	1.40		
Forfeited	—	—		
Oustanding December 31, 2016	2,950,000	$ 0.37	8.3	$389,500
Exercisable December 31, 2016	2,850,000	$ 0.33	8.2	$389,500

The following table presents information related to stock options at December 31, 2016:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$0.33	2,850,000	8.2	2,850,000
$1.40	100,000	—	—
	2,950,000	8.2	2,850,000

Note 10 — Subsequent Events

Preferred Stock

Subsequent to December 31, 2016, the Company's Board of Directors adopted, and the Company's stockholders approved, the Second Amendment to the Company's Certificate of Incorporation (the "Second Amendment"). Pursuant to the Second Amendment, in the event that any holder of shares of Series A Convertible Preferred Stock or Series A-2 Convertible Preferred Stock (collectively, the "Series A/A-2 Preferred Stock") does not participate in a subsequent financing (as defined in the Second Amendment) by purchasing in the aggregate, in such subsequent financing, at least 75% of such holder's pro rata amount, then each share of Series A/A-2 Preferred Stock held by such holder shall automatically be converted into common stock concurrently with the consummation of such subsequent financing. Such conversion is referred to as a "Special Mandatory Conversion."

Series B Convertible Preferred Stock

Subsequent to December 31, 2016, the Company sold an aggregate of 3,446,058 shares of its Series B Convertible Preferred Stock to investors at a price of $1.86 per share for aggregate gross proceeds of $6,409,651. The Company incurred $31,237 of legal costs in connection with the sales, such that the aggregate net proceeds from the sale were $6,378,414. As of the date of the sale, it was determined that the Company, due to an administrative error, inadvertently neglected to file the Amended and Restated Certificate of Incorporation with the Delaware Secretary of State prior to the issuances of Series B

EYENOVIA, INC.

NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

Note 10 — Subsequent Events (continued)

Convertible Preferred Stock. In addition, the Company did not obtain the Board and stockholder approval of the Series B Convertible Preferred Stock and the adoption of the Amended and Restated Certificate of Incorporation. On November 9, 2017, the Board adopted resolutions ratifying each of the issuances of Series B Convertible Preferred Stock, which were then approved by the Company's shareholders. On November 13, 2017, the Company filed a certificate of validation with the Delaware Secretary of State in respect of such ratifications, such that, as of the date of filing, the Series B Convertible Preferred Stock is duly authorized, validly issued, fully paid and nonassessable.

The Series B Convertible Preferred Stock is convertible, at the option of the holder, at any time into shares of common stock on a one-for-one basis, subject to certain adjustments. In the event of any issuances by the Company for less than the in-force conversion price, the Series B Convertible Preferred Stock conversion price shall be reduced on a weighted average basis. Each share of Series B Convertible Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion price: (i) immediately prior to the closing of a firm commitment underwritten initial public offering provided that (A) the aggregate offering price, net of underwriters' discounts and expenses, is at least $2.00 per share of common stock and (B) the aggregate proceeds of such offering are not less than $20,000,000; or (ii) the date specified by written consent or agreement of the holders of at least 75% of the then outstanding shares of preferred stock.

In the event of the Company's liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount per share for each share of preferred stock held by them equal to the sum of (i) the liquidation preference specified for such share of preferred stock and (ii) all declared but unpaid dividends (if any) on such share of preferred stock.

Holders of Series B Convertible Preferred are entitled to non-cumulative dividends at an annual rate of eight percent (8%) when, as and if declared by the Board of Directors out of any assets legally available.

Except as otherwise required by law, the holders of shares of preferred stock shall vote on an as-if-converted-to-common-stock basis with the common stock.

Conversion of Series A Convertible Preferred Stock

Subsequent to December 31, 2016, in connection with the sale of Series B Convertible Preferred Stock, holders of an aggregate of 1,124,488 shares of Series A Convertible Preferred Stock did not participate in such financing by purchasing at least 75% of such holder's pro rata amount. As a result, the Special Mandatory Conversion of the Series A/A-2 Preferred Stock was triggered and, accordingly, such shares of Series A Convertible Preferred stock were automatically converted into an aggregate of 1,124,488 shares of common stock.

Stock Warrants

Subsequent to December 31, 2016, the Company issued a warrant to purchase 232,029 shares of common stock at an exercise price of $0.01 per share to an investor for cash consideration of $431,574. The warrant was sold to an investor for the amount of the investment in excess of what was permitted to be purchased of Series B Convertible Preferred Stock.

Stock Options

Subsequent to December 31, 2016, the Company granted ten-year options to purchase an aggregate of 3,516,534 shares of the Company's common stock. The options have exercise prices as follows: 3,366,534 shares have an exercise price of $0.52 per share and 150,000 shares have an exercise price of $0.62 per share. The options vest as follows: (i) 150,000 shares vested immediately; (ii) 375,000 shares vest monthly over 12 months from the grant date of the award; and (iii) 2,991,534 shares vest monthly over 36 months from the grant date of the award.

EYENOVIA, INC.

Condensed Balance Sheets

	September 30, 2017 (unaudited)	December 31, 2016
Assets		
Current Assets:		
Cash	$ 7,406,034	$ 3,387,288
Prepaid expenses and other current assets	134,841	2,335
Total Current Assets	7,540,875	3,389,623
Property and equipment, net	34,118	43,192
Deferred offering costs	114,237	—
Total Assets	$ 7,689,230	$ 3,432,815
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 321,632	$ 302,031
Accrued expenses and other current liabilities	272,437	121,703
Total Current Liabilities	594,069	423,734
Advances payable	6,409,651	—
Total Liabilities	7,003,720	423,734
Commitments and contingencies (Note 6)	—	—
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 36,000,000 shares authorized;		
Series A Convertible Preferred Stock, 20,000,000 shares designated, 10,996,614 and 12,121,102 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively, liquidation preference of $10,996,614 and $12,121,102 as of September 30, 2017 and December 31, 2016, respectively	1,100	1,212
Series A-2 Convertible Preferred Stock, 5,714,286 shares designated, 2,958,100 shares issued and outstanding as of September 30, 2017 and December 31, 2016, liquidation preference of $4,141,338 as of September 30, 2017 and December 31, 2016	296	296
Series B Convertible Preferred Stock, 10,000,000 shares designated, 0 shares issued and outstanding as of September 30, 2017 and December 31, 2016, liquidation preference of $0 as of September 30, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value, 60,000,000 shares authorized; 9,624,488 and 8,500,000 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	962	850
Additional paid-in capital	17,781,907	17,137,922
Accumulated deficit	(17,098,755)	(14,131,199)
Total Stockholders' Equity	685,510	3,009,081
Total Liabilities and Stockholders' Equity	$ 7,689,230	$ 3,432,815

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Nine Months Ended, September 30,	
	2017	**2016**
Operating Expenses:		
Research and development	$ 2,125,993	$ 1,985,536
General and administrative	842,959	391,945
Total Operating Expenses	2,968,952	2,377,481
Loss From Operations	(2,968,952)	(2,377,481)
Other Income:		
Interest income	1,396	921
Net Loss	$(2,967,556)	$(2,376,560)
Net Loss Per Share–Basic and Diluted	$ (0.35)	$ (0.28)
Weighted Average Number of Common Shares Outstanding–Basic and Diluted	8,514,906	8,500,000

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statement of Changes in Stockholders' Equity
For the Nine Months Ended September 30, 2017
(unaudited)

	Convertible Preferred Stock								
	Series A		Series A-2		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance–January 1, 2017	12,121,102	$1,212	2,958,100	$296	8,500,000	$850	$17,137,922	$(14,131,199)	$ 3,009,081
Issuance of warrants	—	—	—	—	—	—	431,574	—	431,574
Conversion of convertible preferred stock into common stock	(1,124,488)	$ (112)	—	—	1,124,488	112	—	—	—
Stock-based compensation	—	—	—	—	—	—	212,411	—	212,411
Net loss	—	—	—	—	—	—	—	(2,967,556)	(2,967,556)
Balance–September 30, 2017	10,996,614	$1,100	2,958,100	$296	9,624,488	$962	$17,781,907	$(17,098,755)	$ 685,510

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statements of Cash Flows
(unaudited)

	For the Nine Months Ended September 30,	
	2017	**2016**
Cash Flows From Operating Activities		
Net loss	$(2,967,556)	$(2,376,560)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	12,336	6,918
Stock-based compensation	212,411	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(132,506)	(59,932)
Accounts payable	19,601	208,885
Accrued expenses and other current liabilities	117,734	(46,810)
Net Cash Used In Operating Activities	(2,737,980)	(2,267,499)
Cash Flows From Investing Activities		
Purchases of property and equipment	(3,262)	(3,119)
Net Cash Used In Investing Activities	(3,262)	(3,119)
Cash Flows From Financing Activities		
Payment of offering costs	(81,237)	—
Proceeds from sale of Series A-2 Convertible Preferred Stock	—	4,041,336
Proceeds from advances related to Series B Convertible Preferred Stock	6,409,651	—
Proceeds from sale of warrant	431,574	—
Net Cash Provided By Financing Activities	6,759,988	4,041,336
Net Increase in Cash	4,018,746	1,770,718
Cash–Beginning of Period	3,387,288	2,492,611
Cash–End of Period	$ 7,406,034	$ 4,263,329
Supplemental Disclosure of Non-Cash Financing Activities		
Accrual of deferred offering costs	$ 33,000	$ —
Conversion of convertible preferred stock into common stock	$ 112	$ —

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 1 — Business Organization and Nature of Operations

Eyenovia, Inc. ("Eyenovia" or the "Company") is a clinical stage biopharmaceutical company developing a pipeline of ophthalmology products utilizing its patented piezo-print technology to deliver micro-doses (6–8 μL) of active pharmaceutical ingredients (or "micro-therapeutics") topically to the eye. This disruptive micro-dosing technology has the potential to replace traditional macro-dosing applications (e.g. conventional eye droppers), that routinely overdoses or under-doses the topical administration of ophthalmic therapeutics.

In appropriate circumstances, Eyenovia intends to use the regulatory pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which enables a potentially shorter development timeline for its product candidates by allowing it to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. Eyenovia has received written FDA feedback indicating that it can proceed to Phase III clinical trials for two of its lead programs: MicroProst, a novel micro-therapeutic latanoprost formulation for chronic angle closure glaucoma ("CACG"), an indication with no FDA-approved drug treatments; and MicroStat, a fixed combination of micro-therapeutic phenylephrine-tropicamide formulation for mydriasis, also known as pupil dilation for use in eye exams. MicroTears, its over-the-counter ("OTC") treatment for dry eye will not require Phase III studies, and Eyenovia plans to proceed with registration activities.

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual financial statements. In the opinion of management for interim financial information and Article 10 of Regulation S-X, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed financial statements of the Company as of September 30, 2017 and for the nine months ended September 30, 2017 and 2016. The results of operations for the nine months ended September 30, 2017 are not necessarily indicative of the operating results expected for the full year ending December 31, 2017 or any other period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and related disclosures of the Company as of December 31, 2016 and for the year then ended, which are included elsewhere in this registration statement.

Note 2 — Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in Note 2 — Summary of Significant Accounting Policies in the Company's notes to financial statements for the years ended December 31, 2016 and 2015, which are included elsewhere in this registration statement. There have been no material changes to the Company's significant accounting policies, except as disclosed below.

Liquidity and Financial Condition

The Company incurred a net loss of $2,967,556 for the nine months ended September 30, 2017. At September 30, 2017, the Company's working capital and accumulated deficit were $6,946,806 and $17,098,755, respectively. The Company has not yet generated revenues or achieved profitability and it is expected that its research and development and general and administrative expenses will continue to increase and, as a result, the Company will eventually need to generate significant product revenues to achieve profitability.

The Company believes its current cash on hand is sufficient to meet its operating and capital requirements for at least the next twelve months from the date of the issuance of this report. Thereafter, the Company will need to raise further capital, through the sale of additional equity or debt securities, to support its future operations. The Company's operating needs include the planned costs to operate its

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 2 — Summary of Significant Accounting Policies (continued)

business, including amounts required to fund working capital and capital expenditures. The Company's future capital requirements and the adequacy of its available funds will depend on many factors, including the Company's ability to successfully commercialize its products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash.

Cash

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents in the financial statements. As of September 30, 2017 and December 31, 2016, the Company had no cash equivalents.

The Company has cash on deposits in several financial institutions which, at times, may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions. On September 30, 2017 and December 31, 2016, the Company had cash balances in excess of FDIC insurance limits of $7,156,034 and $3,137,288, respectively.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. Weighted average shares outstanding for the nine months ended September 30, 2017 includes the weighted average impact of a warrant to purchase 232,029 shares of common stock because its exercise price was determined to be nominal.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	September 30,	
	2017	2016
Options	6,316,534	2,950,000
Series A Convertible Preferred Stock	10,996,614	12,121,102
Series A-2 Convertible Preferred Stock	2,958,100	—
Series B Convertible Preferred Stock	3,446,058	—
Total potentially dilutive shares	23,717,306	15,071,102

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 3 — Prepaid Expenses and Other Current Assets

As of September 30, 2017 and December 31, 2016, prepaid expenses and other current assets consisted of the following:

	September 30, 2017	December 31, 2016
	(unaudited)	
Prepaid research and development expenses	$ 133,998	$ —
Prepaid insurance expenses	843	2,335
Total prepaid expenses and other current assets	$ 134,841	$ 2,335

Note 4 — Accrued Expenses and Other Current Liabilities

As of September 30, 2017 and December 31, 2016, accrued expenses and other current liabilities consisted of the following:

	September 30, 2017	December 31, 2016
	(unaudited)	
Accrued research and development expenses	$ 173,714	$ 61,000
Accrued legal expenses	20,843	37,597
Accrued rent expense	—	18,590
Accrued professional services	43,169	—
Accrued offering costs	33,000	—
Other	1,711	4,516
Total accrued expenses	$ 272,437	$ 121,703

Note 5 — Advances Payable

During the nine months ended September 30, 2017, the Company sold an aggregate of 3,446,058 shares of its Series B Convertible Preferred Stock to investors at a price of $1.86 per share for aggregate gross proceeds of $6,409,651. The Company incurred $31,237 of legal costs in connection with the sale, such that the aggregate net proceeds from the sale were $6,378,414. As of the date of the sale, it was determined that the Company, due to an administrative error, inadvertently neglected to file the Amended and Restated Certificate of Incorporation with the Delaware Secretary of State prior to the issuances of Series B Convertible Preferred Stock. In addition, the Company did not obtain the Board and stockholder approval of the Series B Convertible Preferred Stock and the adoption of the Amended and Restated Certificate of Incorporation. As a result, the Company classified the gross proceeds from the sale of Series B Convertible Preferred Stock as a non-current liability on its balance sheet as of September 30, 2017. See Note 9 — Subsequent Events — Series B Convertible Preferred Stock for additional details regarding the subsequent ratification of the issuance of Series B Convertible Preferred Stock.

Note 6 — Commitments and Contingencies

Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 6 — Commitments and Contingencies (continued)

The Company, its Chief Executive Officer and members of its Board of Directors are named as defendants in a legal proceeding filed in the United States District Court for the District of New Jersey on September 2, 2014 that has not yet been fully resolved in connection with the Company's Asset Purchase Agreement with Corinthian Ophthalmic, Inc. ("Corinthian"). A shareholder of Corinthian, alleging a fraudulent transfer, is seeking to recover the purchase price of its Corinthian shares and other damages in aggregate amount of approximately $1.1 million. A settlement conference was conducted on July 24, 2017, however, the parties are not close to agreement on a settlement. On October 10, 2017, the Court denied each party's motion for summary judgment. The Company has filed a motion for reconsideration of the Court's decision, with particular focus on the dismissal of the claim against the Company. The motion for reconsideration will be heard on November 20, 2017. A pretrial conference is scheduled with the Court for December 18, 2017. The Company is indemnified by Corinthian and Corinthian's applicable insurance policy provides coverage of $10 million, such that the Company does not expect to incur a material loss as a result of this litigation and, as a result, did not record a loss contingency as of September 30, 2017 or December 31, 2016.

Note 7 — Related Party Transactions

The Company's Chief Executive Officer as well as a member of its Board of Directors are both partners in Private Medical Equity, Inc. ("PME"). The Company and PME are parties to a consulting agreement dated November 4, 2014 that provides for the payment of $33,200 per month to PME in consulting fees for general management and strategy services. Any time spent by PME in excess of the specified amount is billed separately. During the nine months ended September 30, 2017 and 2016, the Company incurred $329,400 and $298,800, respectively, related to the agreement, of which, $263,200 and $239,040, respectively, was included within research and development expenses and $65,800 and $59,760, respectively, was included within general and administrative expenses on the condensed statements of operations.

Since July 2016, the Company pays $3,000 per month to a company controlled by a member of its Board of Directors for office space in New York, New York for its Chief Executive Officer. During the nine months ended September 30, 2017 and 2016, the Company recorded rent expense of $27,000 and $9,000, respectively, related to the office space.

A member of the Company's Board of Directors is part owner in Cura Partners. The Company and Cura Partners are parties to a consulting agreement dated July 6, 2017 that provides for the payment of $9,567 per month, and $250 per hour for any additional work, for advisory services. During the nine months ended September 30, 2017, the Company incurred $25,509 related to the agreement which was included within general and administrative expenses on the condensed statement of operations.

Note 8 — Stockholders' Equity

Authorized Capital

On July 6, 2017, the Company's Board of Directors adopted, and the Company's stockholders approved, the Second Amendment to the Company's Certificate of Incorporation (the "Second Amendment"). Pursuant to the Second Amendment, in the event that any holder of shares of Series A Convertible Preferred Stock or Series A-2 Convertible Preferred Stock (collectively, the "Series A/A-2 Preferred Stock") does not participate in a subsequent financing (as defined in the Second Amendment) by purchasing in the aggregate, in such subsequent financing, at least 75% of such holder's pro rata amount, then each share of Series A/A-2 Preferred Stock held by such holder shall automatically be converted into common stock concurrently with the consummation of such subsequent financing. Such conversion is referred to as a "Special Mandatory Conversion."

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 8 — Stockholders' Equity (continued)

Conversion of Series A Convertible Preferred Stock

On September 27, 2017, in connection with the sale of Series B Convertible Preferred Stock, holders of an aggregate of 1,124,488 shares of Series A Convertible Preferred Stock did not participate in such financing by purchasing at least 75% of such holder's pro rata amount. As a result, the Special Mandatory Conversion of the Series A/A-2 Preferred Stock was triggered and, accordingly, such shares of Series A Convertible Preferred stock were automatically converted into an aggregate of 1,124,488 shares of common stock.

Stock Warrants

On September 27, 2017, the Company issued a warrant to purchase 232,029 shares of common stock at an exercise price of $0.01 per share to an investor for cash consideration of $431,574, which was included within additional paid-in capital on the balance sheet as of September 30, 2017. The warrant was sold to an investor for the amount of the investment in excess of what was permitted to be purchased of Series B Convertible Preferred Stock.

Stock Options

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following approximate assumptions:

	For the Nine Months Ended September 30,	
	2017	2016
Expected term (years)	5.32–10.00	10.00
Risk free interest rate	1.89%–2.31%	1.53%
Expected volatility	130%	131%
Expected dividends	0.00%	0.00%

The weighted average estimated grant date fair value of the stock options granted for the nine months ended September 30, 2017 and 2016 was approximately $0.49 and $0.31 per share, respectively.

The Company recorded stock-based compensation expense related to stock options of $212,411 and $0 during the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, there was $1,483,929 of unrecognized stock-based compensation expense which will be recognized over a weighted average period of 2.6 years.

A summary of the option activity during the nine months ended September 30, 2017 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding January 1, 2017	2,950,000	0.37		
Granted	3,366,534	0.52		
Forfeited	—	—		
Outstanding September 30, 2017	6,136,534	$0.45	8.7	$1,163,153

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 8 — Stockholders' Equity (continued)

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Exercisable September 30, 2017	3,083,692	$ 0.92	7.7	$ 849,369

The following table presents information related to stock options as of September 30, 2017:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$0.33	2,850,000	7.5	2,850,000
$0.52	3,366,534	9.8	228,692
$1.40	100,000	8.9	5,000
	6,316,534	7.7	3,083,692

Note 9 — Subsequent Events

Series B Convertible Preferred Stock

On November 9, 2017, the Board adopted resolutions ratifying each of the issuances of Series B Convertible Preferred Stock, which were then approved by the Company's shareholders. On November 13, 2017, the Company filed a certificate of validation with the Delaware Secretary of State in respect of such ratifications, such that, as of the date of filing, the Series B Convertible Preferred Stock is duly authorized, validly issued, fully paid and nonassessable.

The Series B Convertible Preferred Stock is convertible, at the option of the holder, at any time into shares of common stock on a one-for-one basis, subject to certain adjustments. In the event of any issuances by the Company for less than the in-force conversion price, the Series B Convertible Preferred Stock conversion price shall be reduced on a weighted average basis. Each share of Series B Convertible Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion price: (i) immediately prior to the closing of a firm commitment underwritten initial public offering provided that (A) the aggregate offering price, net of underwriters' discounts and expenses, is at least $2.00 per share of common stock and (B) the aggregate proceeds of such offering are not less than $20,000,000; or (ii) the date specified by written consent or agreement of the holders of at least 75% of the then outstanding shares of preferred stock.

In the event of the Company's liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount per share for each share of preferred stock held by them equal to the sum of (i) the liquidation preference specified for such share of preferred stock and (ii) all declared but unpaid dividends (if any) on such share of preferred stock.

Holders of Series B Convertible Preferred are entitled to non-cumulative dividends at an annual rate of eight percent (8%) when, as and if declared by the Board of Directors out of any assets legally available.

Except as otherwise required by law, the holders of shares of preferred stock shall vote on an as-if-converted-to-common-stock basis with the common stock.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016
(unaudited)

Note 9 — Subsequent Events (continued)

The Series B Convertible Preferred does not contain a redemption provision and an overall analysis of its features performed by the Company determined that it is more akin to equity and therefore, has been classified within stockholders' equity on the balance sheet. While the embedded conversion option ("ECO") is subject to an anti-dilution price adjustment, since the ECO is clearly and closely related to the equity host, it is not required to be bifurcated and accounted for as a derivative liability under ASC 815. The Company determined that the Series B Convertible Preferred did not contain a beneficial conversion feature, since the conversion price exceeded the estimated fair value of the Company's common stock as of the commitment date.

Stock Options

Subsequent to September 30, 2017, the Company granted a ten-year option to a director to purchase 150,000 shares of the Company's common stock. The option has an exercise price of $0.62 per share and vests immediately.

_____ Shares

COMMON STOCK

Ladenburg Thalmann **Roth Capital Partners**

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of our common stock being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the NASDAQ Capital Market, or Nasdq, listing fee.

	Amount to be paid
SEC registration fee	$ *
FINRA filing fee	$ *
Nasdaq initial listing fee	$ *
Transfer agent and registrar fees	$ *
Accounting fees and expenses	$ *
Legal fees and expenses	$ *
Printing and engraving expenses	$ *
Miscellaneous	$ *
Total	$ *

* To be filed by amendment

Item 14. Indemnification of Directors and Officers

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation, as amended, contains provisions eliminating a director's personal liability for monetary damages resulting from a breach of fiduciary duty, except in certain circumstances involving wrongful acts, including:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

- any unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions as provided in Section 174 of the DGCL; or
- for any transaction from which the director derives an improper personal benefit.

These provisions do not limit or eliminate our rights or those of any stockholder to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director's fiduciary duty. These provisions will not alter a director's liability under federal securities laws.

Our bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended, against all expenses and liabilities actually and reasonably incurred by them in connection with their services as our directors and officers. Our bylaws provide that we shall advance the expenses incurred by a director or officer in advance of the final disposition of an action or proceeding. The bylaws also authorize us to indemnify any of our employees or agents and permit us to secure insurance on behalf of any officer, director, employee or agent for any liability arising out of his or her action in that capacity, whether or not the DGCL would otherwise permit indemnification.

We intend to enter into indemnification agreements with our directors and executive officers that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

In addition, the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

Item 15. Recent Sales of Unregistered Securities

The following list sets forth information as to all securities we have sold since March 12, 2014 (date of inception) up to the date of this document, which were not registered under the Securities Act.

In October 2014, we issued 5,000,000 shares of common stock and 5,421,102 shares of Series A preferred stock to Corinthian in connection with our purchase of Corinthian's intellectual property portfolio and related assets.

In October 2014, we issued and sold 3,500,000 shares of common stock to Private Medical Equity, Inc. and PointGuard Partners, LLC for $0.0001 per share.

In March 2015, we issued options to purchase 3,000,000 shares of our common stock with an exercise price of $0.33 per share to our employees, directors and/or consultants under our 2014 Plan.

In April 2015, we issued and sold 5,000,000 shares of Series A preferred stock to Senju Pharmaceutical Co., Ltd. for $1.00 per share in connection with our exclusive license agreement with Senju Pharmacuitical Co., Ltd.

In August 2016, we issued options to purchase 20,000 shares of common stock to a consultant with an exercise price of $0.33 per share under our 2014 Plan.

In October 2016, we issued and sold 2,958,100 shares of Series A-2 preferred stock to five investors for $1.40 per share.

In October 2016, we issued options to purchase 80,000 shares of our common stock to two consultants with an exercise price of $1.40 per share.

In July 2017, we issued and sold 2,779,223 shares of Series B preferred stock to eight investors for $1.86 per share.

In July 2017, we issued options to purchase 3,366,534 shares of our common stock with an exercise price of $0.54 per share to our employees, directors and/or consultants under our 2014 Plan.

In September 2017, we issued and sold 666,836 shares of Series B preferred stock to two investors for $1.86 per share.

In November 2017, we issued an option to purchase 150,000 shares of our common stock with an exercise price of $0.62 per share to a director under our 2014 Plan.

Each of the foregoing issuances was made in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act, or Regulation D promulgated under the Securities Act.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits:

We have filed the exhibits listed on the accompanying Exhibit Index of this registration statement, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

All other schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or notes.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on _____, 2017.

EYENOVIA, INC.

By: _____

Name: Tsontcho Ianchulev

Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Tsontcho Ianchulev and Curt LaBelle, his true and lawful attorneys-in-fact, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments including pre-and post-effective amendments to this registration statement, any subsequent registration statement for the same offering which may be filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and pre-or post-effective amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact or their substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Tsontcho Ianchulev	Chief Executive Officer (Principal Executive Officer)	_____, 2017
_____ _____	_____ (Principal Accounting and Financial Officer)	_____, 2017
_____ Curt LaBelle	Director	_____, 2017
_____ Fred Eshelman	Director	_____, 2017
_____ Ernest Mario	Director	_____, 2017
_____ Shuhei Yoshida	Director	_____, 2017

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Underwriting Agreement.
3.1*	Certificate of Incorporation, as currently in effect.
3.2*	Form of Amendment to the Certificate of Incorporation.
3.3*	By-laws.
5.1*	Opinion of Ellenoff Grossman & Schole LLP.
10.1*	Exclusive License Agreement, dated March 18, 2015, between Eyenovia, Inc. and Senju Pharmaceutical Co., Ltd.
10.2*	Engagement Letter and Offer of Employment, dated July 6, 2017, between Eyenovia, Inc. and Dr. Tsontcho Ianchulev.
10.3*	Engagement Letter and Offer of Employment, dated July 6, 2017, between Eyenovia, Inc. and Luke Clauson.
10.4*	Engagement Letter and Offer of Employment, dated July 6, 2017, between Eyenovia, Inc. and Jennifer G. Clasby.
10.5*	Engagement Letter for Professional Services, dated July 6, 2017, between Eyenovia, Inc. and Dr. Curt LaBelle.
10.6*	Amended and Restated Investors' Rights Agreement, dated September 27, 2017, between Eyenovia, Inc. and investors party thereto.
10.7*	Amended and Restated Right of First Refusal and Co-Sale Agreement, dated September 27 2017, between Eyenovia, Inc. and investors party thereto.
10.8*	Amended and Restated Voting Agreement, dated September 27, 2017, between Eyenovia, Inc. and investors party thereto.
10.9*	Correction Letter, dated November 8, 2017, between Eyenovia, Inc. and Dr. Tsontcho Ianchulev.
10.10*	Master Consulting Services Agreement, dated November 4, 2014, between Eyenovia, Inc. and Private Medical Equity, Inc.
10.11*	Master Consulting Services Agreement, dated November 4, 2014, between Eyenovia, Inc. and Point Guard Partners, LLC.
23.1*	Consent of Marcum LLP.
23.2*	Consent of Ellenoff Grossman & Schole LLP (included in Exhibit 5.1).
24*	Power of Attorney (included on signature page of this Registration Statement).

* To be filed by amendment.