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As confidentially submitted to the Securities and Exchange Commission on September 11, 2015. 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

GEMPHIRE THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**47-2389984**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Mina Sooch
Chief Executive Officer
Gemphire Therapeutics Inc.
43334 Seven Mile Road, Suite 1000
Northville, Michigan 48167
(248) 681-9815
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

With copies to:

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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. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) 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. o

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. o

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 number of the earlier effective registration statement for the same offering. o

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class Of Securities To Be Registered	Proposed Maximum Aggregate Offering Price[1][2]	Amount of Registration Fee
Common Stock, par value $0.001 per share	$	$

(1) Includes the offering price of any additional shares of common stock that the underwriters have the right to purchase to cover over-allotments, if any.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933.

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 of 1933, 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.

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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 , 2015

PRELIMINARY PROSPECTUS

Shares

Gemphire Therapeutics Inc.

Common Stock

We are offering shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price of our common stock to be between $ and $ per share. We intend to apply to list our common stock on the NASDAQ Global Market under the symbol "GEMP".

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 11 of this prospectus.

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

	PER SHARE	TOTAL
Public Offering Price	$	$
Underwriting Discounts and Commissions[1]		
Proceeds to Gemphire, before expenses		

[1] We have agreed to reimburse the underwriters for certain expenses. See "Underwriting."

We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ million, and the total proceeds to us, before expenses will be $ million.

The underwriters expect to deliver the shares of common stock to purchasers on or about , 2015.

Joint Book-Running Managers

Jefferies **Cowen and Company**

Co-Manager

Roth Capital Partners

Prospectus dated , 2015

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We have not authorized anyone to provide you with information that is different from that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell our common stock, and seeking offers to buy our common stock, only in jurisdictions where such offers and sales are permitted. You should assume that the information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not and the underwriters have not 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 in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Through and including , 2015 (25 days after the date of this prospectus), all dealers effecting 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 the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements, related notes and other financial information elsewhere in this prospectus, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to "we," "us," "the Company" and "our" refer to Gemphire Therapeutics Inc.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease. Dyslipidemia is generally characterized by an elevation of low-density lipoprotein cholesterol (LDL-C), or bad cholesterol, triglycerides, or fat in the blood, or both. We are developing our product candidate gemcabene (CI-1027), a novel, once-daily, oral therapy, for patients who are unable to achieve normal levels of LDL-C or triglycerides with currently approved therapies, primarily statin therapy. Gemcabene's dual mechanism of action is designed to both inhibit the production of fatty acids and cholesterol in the liver and enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma. Gemcabene has been tested as monotherap and in combination with statins and other drugs in 895 subjects, which we define as healthy volunteers and patients, across 18 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

Cardiovascular disease is a major health concern, causing more deaths globally than any other disease. Dyslipidemia is generally viewed as an important predictor of cardiovascular events including heart attack and stroke, and a cause of cardiovascular disease. It comprises one of the largest therapeutic areas with annual worldwide drug sales of approximately $22 billion in 2013. We estimate more than 40% of Americans have LDL-C or triglycerides, or both, above a normal range. Statins, such as Lipitor, marketed by Pfizer Inc. (Pfizer), and Crestor, marketed by AstraZeneca Pharmaceuticals LP (AstraZeneca), among others, are standard of care for LDL-C lowering, while fibrates, prescription fish oils and niacin are standar of care for triglyceride lowering. Although these drugs are highly prescribed and capable of reducing LDL-C and triglyceride levels, many patients are unable to effectively manage their dyslipidemia with currently approved therapies and are in need of better treatment alternatives. For example, approximately 40% of patients on statins are unable to meet their LDL-C lowering goal, and doubling a statin dose has shown to incrementally lower LDL-C levels by a nominal percentage (approximately 6% based on historical evidence), while increasing safety and tolerability concerns. An even higher percentage of patients with severe hypertriglyceridemia do not achieve triglyceride levels low enough to reduce the risk of developing co-morbidities such as pancreatitis.

We believe gemcabene possesses a differentiated product profile compared to other therapies in the market and in clinical development. Key attribute of our product candidate include the following:

- **Cost-effective, once-daily, oral therapy.** Gemcabene is a small molecule formulated as a tablet and is cost effective to manufacture. As a once-daily, oral therapy, gemcabene, if approved, would be more convenient than other non-statin therapies, many of which require frequent injections or multiple daily doses.

- **Promising safety and tolerability.** Gemcabene was observed to be well tolerated in 895 subjects across 18 Phase 1 and Phase 2 trial both as monotherapy and in combination with statins. No subjects died and no subjects experienced a serious adverse event (SAE) that was considered to be related to gemcabene. Adverse events (AEs) reported were generally mild to moderate in intensity. Gemcabene di not appear to increase the reporting of myalgia (muscle pain) when added to statin

therapy and no treatment related events of myalgia were reported in any gemcabene monotherapy arm in the dyslipidemia trials.

- **Significant lipid-lowering of LDL-C, high-sensitivity C-reactive protein (hsCRP) and triglycerides.** In Phase 2 trials, patients with hypercholesterolemia treated with gemcabene as monotherapy were observed to have significantly lowered LDL-C by approximately 30% from baseline and significantly lowered hsCRP by approximately 40% from baseline. In addition, patients with hypertriglyceridemia (³200 mg/dL) were observed to have significantly lowered triglycerides by approximately 40%, and based on post-hoc analysis, gemcabene was observed to lower triglycerides by up to 60% in patients with severe triglyceride levels (³500 mg/dL). Our product candidate's ability to meaningfully lower levels of multiple key lipids attributable to cardiovascular disease may expand its use across multiple indications within the dyslipidemia market.

- **Additive effect in combination with statins.** In a Phase 2 trial in patients with uncontrolled hypercholesterolemia while on stable statin therapy, gemcabene was observed to significantly lower LDL-C by an additional 25% to 31% from baseline. This data indicates that gemcabene may better treat a large population of patients who are unable to reach their lipid goal with statins and other currently prescribed therapies.

- **No drug-drug interactions when combined with high-intensity statin doses.** In two Phase 1 trials, gemcabene was tested in combination with high-intensity statin doses, 80 mg simvastatin and 80 mg atorvastatin. No clinically relevant drug-drug interactions were observed. In addition, gemcabene has been formulated as a fixed-dose combination tablet with various atorvastatin doses, which may offer additional convenience and compliance to patients.

We are initially pursuing gemcabene in the following four indications as a treatment in addition to maximally tolerated statin therapy for patients who are unable to reach their lipid-lowering goals:

- homozygous familial hypercholesterolemia (HoFH), a rare genetic lipid disorder which results in elevated LDL-C usually due to mutations in both alleles, a pair of genes on a chromosome responsible for a specific trait, of the LDL-receptor gene;

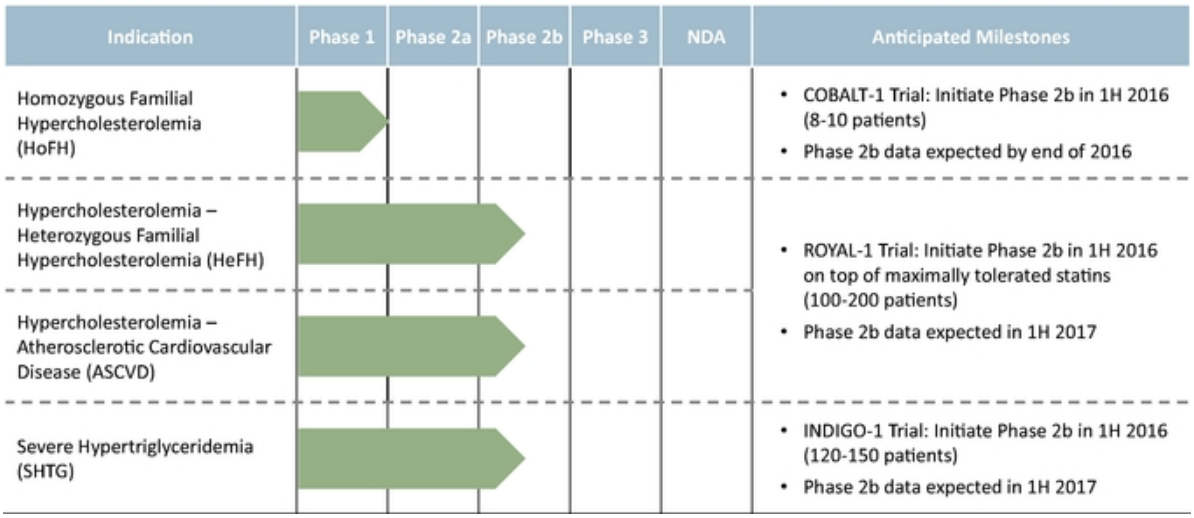
- heterozygous familial hypercholesterolemia (HeFH), a more prevalent genetic lipid condition which results in elevated LDL-C usually due to a mutation in one allele of the LDL-receptor gene;

- atherosclerotic cardiovascular disease (ASCVD), patients with hypercholesterolemia, or patients with elevated LDL-C who have had or are at risk for a cardiovascular event, such as heart attack or stroke; and

- severe hypertriglyceridemia (SHTG), in which patients with elevated triglycerides are at an increased risk of developing co-morbidities such as pancreatitis.

We are pursuing HoFH given that gemcabene has recently received orphan drug designation for this indication. We believe we can design an efficient development plan to provide a new treatment alternative for those patients. Furthermore, we believe that gemcabene's potential ability to treat patients in the most severe segment of the dyslipidemia market, HoFH, will enhance brand awareness among key thought leaders and physicians. We are developing gemcabene for HeFH, ASCVD and SHTG given gemcabene's: (1) promising clinical data in these indications; (2) cost-effective manufacturing process; (3) convenient oral dosing; (4) viability as adjunct combination therapy; and (5) large commercial potential. In the first half of 2016, we expect to initiate three Phase 2b trials for gemcabene in HoFH, hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins, and SHTG.

Gemcabene Pipeline Indications



Our company was co-founded by former Pfizer employees, Dr. Charles Bisgaier and David Lowenschuss, who were responsible for licensing exclusive worldwide rights to gemcabene from Pfizer in April 2011. Prior to co-founding the original Esperion Therapeutics, Inc. (Esperion) in 1998, which was acquired by Pfizer in 2004, Dr. Bisgaier worked at Parke-Davis, a division of Warner-Lambert Company from 1990 to 1998, and was instrumental in the discovery and development of gemcabene, as well as the development of Lipitor and Lopid. Many of our employees and consultants have been involved in the historical development of gemcabene and other innovative dyslipidemia product candidates in development, including ETC-216, a synthetic HDL based on ApoAI-Milano (developed by the original Esperion, Pfizer and currently The Medicines Company), ACP-501 (developed by AlphaCore Pharma, later acquired by AstraZeneca) and ETC-1002 (developed by the original Esperion, Pfizer and the current Esperion). We have organized a medical advisory board with key opinion leaders including Drs. John Kastelein, Evan Stein, Robert Hegele and Dirk Blom who are recognized worldwide experts in the drug development of lipid-lowering therapies. The management team, led by our CEO Mina Sooch, has significan experience in operating and financing biopharmaceutical companies with a successful track record of discovering, developing and commercializing treatments in the cardiovascular and orphan markets.

Our Strategy

Our goal is to become a leading cardio-metabolic biopharmaceutical company that develops and commercializes best-in-class therapies for patients, and provides attractive solutions for physicians and payors.

The core elements of our strategy to achieve our goal are the following:

§ ***Advance the late-stage clinical development of gemcabene across multiple target indications.*** We are focused on a broad spectrum of indications for dyslipidemia patients ranging from the orphan indication HoFH to more prevalent conditions, such as HeFH, ASCVD and SHTG. We believe that these indications present favorable regulatory pathways and the highest likelihood of commercial success. During the first half of 2016, we plan to initiate three Phase 2b trials with top-line results expected starting at the end of 2016 continuing through 2017.

§ ***Pursue oral combination opportunities for gemcabene.*** Oral combination therapy is the current paradigm for the treatment of dyslipidemia, as patients typically require multiple drugs to address their dyslipidemia as well as other co-morbidities. As part of our development strategy, we plan to

formulate and manufacture gemcabene in fixed-dose combination with statins and/or other lipid-lowering agents.

- ***Continue to build out our patent portfolio for gemcabene.*** We believe our patents and patent applications provide us with a significant competitive advantage. We have 24 issued patents and 18 pending patent applications for gemcabene in the United States and internationally directed to formulations, compositions, methods of use and methods of manufacturing. We intend to aggressively prosecute and defend our patent portfolio and pursue new patents in order to ensure the long term commercial success of gemcabene.

- ***Maximize the global commercial value of gemcabene.*** We have retained all commercial and manufacturing rights to gemcabene. We believe we could independently commercialize gemcabene for the treatment of patients with HoFH in the United States with a targeted sales force and would seek commercial partners outside of the United States. For larger indications, such as HeFH, ASCVD and SHTG, we would assess partnership opportunities for Phase 3 development and the worldwide commercialization of gemcabene.

- ***Leverage the expertise and experience of our management team to evaluate future in-licensing and acquisition opportunities.*** Across our leadership team, we have discovered and/or developed Lipitor, Lopid, ETC-1002, ETC-216, ACP-501, Vaprisol and PNT-2258, and commercialized many lipid regulating and orphan drugs including Crestor, Myalept and Lynparza. Our team is well-qualified to identify and in-license or acquire clinical-stage cardio-metabolic assets, and we intend to evaluate these opportunities to diversify our pipeline and generate long-term growth.

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 only losses since inception and have not generated any revenue, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

- We currently depend entirely on the success of gemcabene, our only product candidate.

- The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

- We may fail to demonstrate safety and efficacy for gemcabene or see undesirable side effects that were not previously identified.

- We may experience difficulties in clinical development, such as the enrollment of patients in clinical trials, which could result in increased costs to us and could delay our development timeline.

- We may never receive marketing approval for, or successfully commercialize, gemcabene for any indication.

- Gemcabene is subject to a partial clinical hold with respect to clinical trials of longer than six months in duration, which may lead to significant delays or the failure of gemcabene to obtain marketing approval.

- Changes in regulatory requirements or U.S. Food and Drug Administration (FDA) guidance, or unanticipated events during our clinical trials, may result in changes to clinical trial protocols or additional clinical trial requirements, such as the initiation or completion of a cardiovascular outcome trial.

- We rely on third-party clinical research organizations, suppliers and manufacturers, and we are not able to directly control all aspects of our preclinical studies, clinical trials and drug manufacturing.

- We depend on intellectual property licensed from Pfizer for gemcabene, and the termination of this license would harm our business.

- If we are unable to adequately protect our proprietary technology or maintain issued patents sufficient to protect gemcabene or any futur product candidate, others could compete against us more directly.
- We need to establish sales and marketing capabilities or enter into agreements with third parties to sell and market gemcabene, if approved, for successful commercialization.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our future success depends on our ability to attract and retain our executives and key personnel.
- Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern. We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Corporate Information

We were formed in Michigan as Michigan Life Therapeutics, LLC (MLT) in November 2008. In October 2014, we incorporated a new entity under the name Gemphire Therapeutics Inc. in Delaware. MLT then merged with and into Gemphire, with Gemphire as the surviving entity. The purpose of the merger was to change the jurisdiction of our incorporation from Michigan to Delaware and to convert from a limited liability company to a corporation. Our principal executive offices are located at 43334 Seven Mile Road, Suite 1000, Northville, Michigan 48167, and our telephone number is (248) 681-9815. Our corporate website address is www.gemphire.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus contains references to trademarks belonging to us and other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. As an "emerging growth company" we are:

- permitted to present 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 in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- permitted to take advantage of reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- permitted to take advantage of exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth

company prior to the end of such five-year period. We have elected to take advantage of certain of the reduced disclosure obligations in the registratio statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

The Offering

Common stock offered by us	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 common stock.
Common stock to be outstanding after this offering	shares (shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	We estimate that we will receive net proceeds of approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additiona shares in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with cash and cash equivalents, to fund development costs associated with Phase 2b clinical trials of gemcabene for our target indications our planned end of Phase 2 meeting with the FDA, preclinical studies and related activities for gemcabene and the balance for general corporate purposes. See "Use of Proceeds."
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.
Proposed NASDAQ Global Market symbol	"GEMP"
Directed share program	At our request, the underwriters have reserved up to % of the shares of our common stock offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees and other individuals associated with us and members of their respective families. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. The underwriters will receive the same underwriting discount on any shares purchased by these investors as they will on any other shares sold to the public in this offering. Any shares purchased by such investors will be subject to the lock-up restrictions described in the section titled "Underwriting."

The number of shares of our common stock to be outstanding after this offering is based on 14,040,684 shares of common stock outstanding as of June 30, 2015 and excludes:

- 318,522 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2015 at an exercise price of $0.431 per share;
- 266,600 shares of common stock issuable upon the exercise of stock options granted after June 30, 2015 at an exercise price of $0.68 per share;
- shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan (the 2015 Plan), which will be amended and restated in connection with this offering, and shares of common stock reserved for future issuance under our 2015 Employee Stock Purchase Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under these plans; and
- shares issuable to holders of our convertible bridge notes issued after June 30, 2015 upon conversion thereof.

Unless otherwise indicated, all information contained in this prospectus assumes the following:

- the conversion of all of our convertible preferred stock outstanding as of June 30, 2015 into 2,325,581 shares of common stock immediately prior to the closing of this offering;
- a 1-for- reverse split of our common stock to be effected prior to the completion of this offering;
- the issuance of shares of common stock pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy" immediately prior to the closing of the offering;
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock; and
- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prio to the closing of this offering.

Summary Financial Data

The following summary financial data should be read together with our financial statements and related notes, "Capitalization," "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus. The summary financial data in this section are not intended to replace our financial statements and the related notes.

We derived the summary statements of operations data for the years ended December 31, 2013 and 2014 from our audited financial statements and related notes appearing elsewhere in this prospectus. We derived the summary statements of operations data for the six months ended June 30, 2014 and 2015 and the summary balance sheet data as of June 30, 2015 from our unaudited interim financial statements appearing elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as our audited financial statements and include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information set forth in those statements. Our historical results for any prior period are not necessarily indicative of results expected in any future period, and our interim results are not necessarily indicative of results for a full year or any other period.

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
			(unaudited)	
	(in thousands, except share and per share amounts)			
Statements of Operations Data:				
Operating expenses:				
General and administrative	$ 97	$ 214	$ 48	$ 1,133
Research and development	1	52	42	1,158
Acquired in-process research and development	—	—	—	908
Total operating expenses	98	266	90	3,199
Loss from operations	(98)	(266)	(90)	(3,199)
Interest expense	(13)	(55)	(10)	(690)
Other income (expense)	—	1	—	(1)
Net loss	(111)	(320)	(100)	(3,890)
Adjustment to redemption value on Series A convertible preferred stock	—	—	—	(2,666)
Net loss attributable to common stockholders	$ (111)	$ (320)	$ (100)	$ (6,556)
Net loss per share attributable to common stockholders, basic and diluted[(1)]		$ (0.07)		$ (0.83)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted[(1)]		4,746,648		7,902,438
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]		$		$
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]				

(1) See note 10 to our financial statements appearing elsewhere in this prospectus for further details on the calculation of net loss per share attributable to common stockholders, basic and diluted, and pro forma net loss per share attributable to common stockholders, basic and diluted, and the weighted-average number of shares used in computation o the per share amounts.

	June 30, 2015		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)(3)
		(unaudited) (in thousands)	
Balance Sheet Information:			
Cash and cash equivalents	$ 2,189	$	$
Working capital	12		
Total assets	2,221		
Total liabilities	662		
Series A convertible preferred stock	7,651		
Accumulated deficit	(6,104)		
Total stockholders' (deficit) equity	(6,092)		

(1) Pro forma balance sheet data reflects (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 2,325,581 shares of common stock immediately prior to the closing of this offering, (ii) the issuance of shares of common stock immediately prior to the closing of the offering pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy", (iii) the immediate vesting of 2,008,097 shares of restricted stock valued at $56,227 held by certain employees upon the closing of this offering and (iv) the filing of our amended and restated certificate of incorporation immediately prior to the closing of this offering.

(2) Pro forma as adjusted balance sheet data reflects (i) the pro forma adjustments set forth above in footnote (1) and (ii) the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) each of our cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming that the number of shares offered by us remains the same and after deducting estimated underwriting discounts and commissions. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of our cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions. The information above is illustrative only, and our balance sheet following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of the offering determined at the pricing of this offering.

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, related notes and other financial information appearing elsewhere in this prospectus 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to the Development of Gemcabene or any Future Product Candidate

We currently depend entirely on the success of gemcabene, our only product candidate. We may never receive marketing approval for, or successfully commercialize, gemcabene for any indication.

We currently have only one product candidate, gemcabene, in clinical development, and our business depends on its successful clinical development, regulatory approval and commercialization. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of a drug product are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, where regulations differ from country to country. We are not permitted to market gemcabene in the United States until we receive approval of a new drug application (NDA) from the FDA or in any foreign countries until we receive the requisite approval from such countries. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities or received marketing approval for gemcabene. Before obtaining regulatory approval for the commercial sale of gemcabene for a particular indication, we must demonstrate through preclinical testing and clinical trials that gemcabene is safe and effective for use in that target indication. This process can take many years and may be followed by post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we raise in this offering. Of the large number of drugs in development in the United States, only a small percentage of drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to complete development of gemcabene, we cannot assure you that gemcabene will be approved or commercialized.

Obtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of gemcabene for many reasons, including:

- § the data collected from preclinical studies and clinical trials of gemcabene may not be sufficient to support the submission of an NDA;
- § we may not be able to demonstrate to the satisfaction of the FDA that gemcabene is safe and effective for any indication;
- § the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA for approval;
- § the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- § the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that gemcabene's clinical and other benefits outweigh its safety risks;
- § the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- § the FDA may not accept data generated at our clinical trial sites;
- § the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA may require development of a risk evaluation and mitigation strategy (REMS) as a condition of approval;
- the FDA may identify deficiencies in the manufacturing processes or facilities of third party manufacturers with which we enter into agreements for clinical and commercial supplies; or
- the FDA may change its approval policies or adopt new regulations.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

The results from the prior preclinical studies and clinical trials for gemcabene discussed elsewhere in this prospectus may not necessarily be predictive of the results of future preclinical studies or clinical trials. Even if we are able to complete our planned clinical trials of gemcabene according to our current development timeline, the results from our prior clinical trials of gemcabene may not be replicated in these future trials. Many companies in the pharmaceutical and biotechnology industries (including those with greater resources and experience than us) have suffered significant setbacks in late-stage clinical trials after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported AEs. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain FDA approval. If we fail to produce positive results in our clinical trials of gemcabene, the development timeline and regulatory approval and commercialization prospects for gemcabene and our business and financial prospects, would be adversely affected.

Further, gemcabene may not be approved even if it achieves its primary endpoint in Phase 3 registration trials. The FDA or non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. Furthermore, any of these regulatory authorities may also approve our product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials.

We plan to commence Phase 2b clinical trials in the first half of 2016 and pursue further clinical trials as described elsewhere in this prospectus. If successful, we plan to eventually seek regulatory approvals of gemcabene initially in the United States, Canada and Europe, and we may seek approvals in other geographies. Before obtaining regulatory approvals for the commercial sale of any product candidate for any target indication, we must demonstrate with substantial evidence gathered in preclinical studies and adequate and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication. We cannot assure you that the FDA or non-U.S. regulatory authorities would consider our planned clinical trials to be sufficient to serve as the basis for approval of gemcabene for any indication. The FDA and non-U.S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that gemcabene is safe and effective. If we are required to conduct clinical trials of gemcabene in addition to those we have planned prior to approval, such as a cardiovascular outcome trial, we will need substantial additional funds, and we cannot assure you that the results of any such outcome trial or other clinical trials will be sufficient for approval.

If clinical trials of gemcabene or any future product candidate fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of gemcabene, we must complete preclinical development (including, but not limited to, two-year rat and mouse carcinogenicity studies), and supportive pharmacology studies and Phase 2b and Phase 3 trials to demonstrate the safety and efficacy in humans. Preclinical development and extensive clinical trials will also be required before obtaining marketing approval from regulatory authorities for any other product candidate we may pursue in the future. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of development.

We, or our future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could result in increased development costs, delay, limit or prevent our ability to receive marketing approval or commercialize gemcabene or any other product candidate we may pursue in the future, including:

- § regulators or institutional review boards (IRBs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- § government or regulatory delays and changes in regulatory requirements, policy and guidelines may require us to perform additional clinical trials or use substantial additional resources to obtain regulatory approval;
- § we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- § clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- § the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- § our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- § our patients or medical investigators may be unwilling to follow our clinical trial protocols;
- § we might have to suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- § the cost of clinical trials may be greater than we anticipate;
- § the supply or quality of any product candidate or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- § the product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We or our future collaborators may not be able to initiate or continue clinical trials for gemcabene or any future product candidate if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States. Orphan indications, in particular, have small populations, and it may be difficult for us to locate and enroll sufficient patients in trials for orphan-designated indications. Patient enrollment can be affected by many factors, including:

- § severity of the disease under investigation;

- availability and efficacy of medications already approved for the disease under investigation;
- eligibility criteria for the trial in question;
- competition for eligible patients with other companies conducting clinical trials for product candidates seeking to treat the same indication or patient population;
- our payments for conducting clinical trials;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

We expect that our Phase 2b clinical trials of gemcabene will commence in the first half of 2016 and may take up to 12 months to enroll; however, we cannot assure you that our timing and enrollment assumptions are correct given the above factors. Our inability to enroll a sufficient number of patients for our clinical trials or retain sufficient enrollment through the completion of our trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and cause our stock price to decline.

We or others could discover that gemcabene or any product candidate we may pursue in the future lacks sufficient efficacy, or that it causes undesirable side effects that were not previously identified, which could delay or prevent regulatory approval or commercialization.

Because gemcabene has been tested in relatively small patient populations and for limited durations to date, it is possible that our clinical trials have or will indicate an apparent positive effect of gemcabene that is greater than the actual positive effect, if any, or that additional and unforeseen side effects may be observed as its development progresses. The discovery that gemcabene lacks sufficient efficacy, or that it causes undesirable side effects (including side effects not previously identified in our completed clinical trials), could cause us or regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the denial of regulatory approval by the FDA or other non-U.S. regulatory authorities for any or all targeted indications. The most common events reported to date have been headache, weakness, nausea, dizziness, upset stomach, infection, abnormal bowel movements, myalgia and abnormal kidney function tests.

The discovery that gemcabene or any future product candidate lacks sufficient efficacy or that it causes undesirable side effects that were not previously identified could prevent us from commercializing such product candidate and generating revenues from its sale. In addition, if we receive marketing approval for gemcabene and we or others later discover that it is less effective, or identify undesirable side effects caused by gemcabene:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way this product is administered, conduct additional clinical trials or change the labeling or distribution of the product (including REMS);
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we could be sued and held liable for harm caused to patients;
- the product may be rendered less competitive and sales may decrease; or
- our reputation may suffer generally both among clinicians and patients.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant, or any, revenues from the sale of the product.

Changes in regulatory requirements or FDA guidance, or unanticipated events during our clinical trials, may result in changes to clinical trial protocols or additional clinical trial requirements, such as the initiation or completion of a cardiovascular outcome trial, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements or FDA guidance, or unanticipated events during our clinical trials, may force us to amend clinical trial protocols or the FDA may impose additional clinical trial requirements. Amendments to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our Phase 2b or Phase 3 trials, or if we are required to conduct additional clinical trials, such as a cardiovascular outcome trial prior to approval, the commercial prospects for gemcabene may be harmed and our ability to generate product revenue will be delayed. If the FDA requires us to conduct a cardiovascular outcome trial sooner than planned, we may not be able to identify and enroll the requisite number of patients in that trial. Even if we are successful in enrolling patients in a cardiovascular outcome trial, we may not ultimately be able to demonstrate that lowering LDL-C levels using gemcabene provides patients with an incremental lowering of cardiovascular disease risks, and our failure to do so may delay or prejudice our ability to obtain FDA approval for gemcabene. Our current development timeline for gemcabene does not contemplate the completion of a cardiovascular outcome trial prior to approval, and such trial would be costly and time-consuming and, regardless of the outcome, would adversely affect our development timeline and financial condition.

We have not generated any revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage product candidate, gemcabene, and we do not currently have any other products or product candidates. We do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize, gemcabene. Our ability to generate revenue depends on a number of factors, including our ability to:

- initiate and successfully complete preclinical carcinogenicity studies to remove the partial clinical hold to allow us to complete longer term registration trials for marketing approval of gemcabene;
- obtain favorable results from and complete the clinical development of gemcabene for our planned indications, including successful completion of our Phase 2b and Phase 3 trials for these indications;
- submit an application to regulatory authorities for gemcabene and receive marketing approval in the United States and foreign countries;
- contract for the manufacture of commercial quantities of gemcabene, if approved, at acceptable cost levels;
- establish sales and marketing capabilities to effectively market and sell gemcabene, if approved, in the United States and the European Union, alone or with a pharmaceutical partner; and
- achieve market acceptance of gemcabene in the medical community and with third-party payors.

Even if gemcabene is approved for commercial sale in one or all of the initial indications that we are pursuing, it may not gain market acceptance or achieve commercial success. In addition, we anticipate incurring significant costs associated with commercializing gemcabene. Moreover, some of the indications we are targeting are small enough to be eligible for orphan drug designation, and our potential patient market is relatively smaller than other drugs, and therefore the price of gemcabene may need to be higher

than other drugs. We may not achieve profitability soon after generating product revenue, if ever, and may be unable to continue operations without continued funding.

If we fail to receive regulatory approval for any of our planned indications for gemcabene or fail to develop additional product candidates, our commercial opportunity will be limited.

We are initially focused on the development of gemcabene for our target indications. However, we cannot assure you that we will be able to obtain regulatory approval of gemcabene for any indication, or successfully commercialize gemcabene, if approved. If we do not receive regulatory approval for, or successfully commercialize, gemcabene for one or more of our targeted indications, our commercial opportunity will be limited.

We may pursue clinical development of additional product candidates. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of this offering and are prone to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any additional product candidates through the development process.

Even if we obtain FDA approval to market additional product candidates, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited.

We depend on intellectual property licensed from Pfizer for gemcabene, and the termination of this license would harm our business.

Pfizer has granted us a worldwide exclusive license to make, use, sell, offer for sale and import the clinical product candidate gemcabene, along with certain intellectual property for the purposes of development and commercialization of gemcabene. We or Pfizer may terminate this license in the event of a material breach that remains uncured for 30 days from the date that the breaching party is provided with notice of such breach, provided that if such breach is capable of being cured, the cure period may be extended up to an additional 60 days, or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate this license in the event that we, or any of our affiliates, consent, challenge, support or assist any third party to contest or challenge Pfizer's ownership of or rights in, or the validity, enforceability or scope of, any of the patents licensed under this license. Additionally, Pfizer may revoke the license if we are unable to adequately commercialize gemcabene by April 2021. See "Business — Pfizer Licensing Terms" for additional information regarding our license agreement with Pfizer.

Disputes may arise between us and Pfizer regarding intellectual property subject to this license agreement, including with respect to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of Pfizer that is not subject to the licensing agreement;
- the amount and timing of milestone and royalty payments;
- the rights of Pfizer under the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Pfizer and us and our partners.

Any disputes with Pfizer may prevent or impair our ability to maintain our current licensing arrangement. We depend on the intellectual property licensed from Pfizer to develop and commercialize gemcabene. Termination of our license agreement could result in the loss of significant rights and would harm our ability

to further develop and commercialize gemcabene. In addition, Pfizer has a non-exclusive, sub licensable, royalty-free right and license for non-commercial research or development purposes to intellectual property rights relating to gemcabene that are developed by us after the effective date of the license with Pfizer.

The development of gemcabene or pursuit of any future product candidate for broad patient populations will be more costly and commercial pricing for any approved indication would likely be lower.

Although we are initially pursuing development of gemcabene for the treatment of patients with HoFH, we believe that gemcabene may be useful for the treatment of elevated lipid and tryglyceride levels in broader patient populations, including HeFH, ASCVD and SHTG. Expanding our development and commercialization of gemcabene or any future product candidate in these or other broader patient populations would be more costly and take longer to complete and would be subject to development and commercialization risks that may not be applicable to HoFH orphan indication.

Specifically, this may involve clinical trials with larger numbers of patients possibly taking the drug for longer periods of time. In addition, we believe that the FDA and, in some cases, the European Medicines Agency (EMA) may require a clinical outcome trial demonstrating a reduction in cardiovascular events either prior to or after the submission of an application for marketing approval for the broader LDL-C indications. Clinical outcome trials are particularly expensive and time consuming to conduct because of the larger number of patients required to establish that the drug being tested has the desired effect. It may also be more difficult for us to demonstrate the desired outcome in these trials than to achieve validated surrogate endpoints. In addition, in considering approval of gemcabene for broader patient populations with less severely elevated lipid levels, the FDA and other regulatory authorities may place greater emphasis on the side effect and risk profile of the drug in comparison to the drug's efficacy and potential clinical benefit than in smaller, more severely afflicted patient populations. These factors may make it more difficult for us to achieve marketing approvals of gemcabene for these broader patient populations.

Moreover, if we pursue and are able to successfully develop and obtain marketing approval of gemcabene and any future product candidate in broader patient populations, we likely will not be able to obtain the same pricing level that we expect to obtain for orphan indications. The pricing of some drugs intended for orphan populations is often related to the size of the patient population, with smaller patient populations often justifying higher prices. If the pricing is lower in broader patient populations, we may not be able to maintain higher pricing in the population of more severely afflicted patients. This would lead to a decrease in revenue from sales to more severely afflicted patients and could make it more difficult for us to achieve or maintain profitability.

We do not have drug research or discovery capabilities and will need to acquire or license product candidates from third parties to expand our product candidate pipeline.

We currently have no drug research or discovery capabilities. Accordingly, if we are to expand our product candidate pipeline beyond gemcabene, we will need to acquire or license product candidates from third parties. We will face significant competition in seeking to acquire or license promising product candidates. Many of our competitors for such promising product candidates may have significantly greater financial resources and more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products, and thus, may be a more attractive option to a potential licensor than us. If we are unable to acquire or license additional promising product candidates, we will not be able to expand our product candidate pipeline.

If we are able to acquire or license other product candidates, such license agreements will likely impose various obligations upon us, and our licensors may have the right to terminate the license thereunder in the event of a material breach or, in some cases, at will. A termination of future licenses could result in our loss of the right to use the licensed intellectual property, which could adversely affect our ability to develop and commercialize a future product candidate, if approved, as well as harm our competitive business position and our business prospects.

We may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are currently focusing only on development programs that we identify for specific indications for gemcabene. As a result, we may forego or delay pursuit of opportunities for other indications, or with other potential product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications or future product candidates may not yield any commercially viable product. If we do not accurately evaluate the commercial potential or target market for gemcabene, we may not gain approval or achieve market acceptance of that candidate, and our business and financial results will be harmed.

Risks Related to our Financial Position and Need for Additional Capital

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

Since inception, we have incurred only operating losses. Our net losses were $0.1 million, $0.3 million and $3.9 million for the years ended December 31, 2013 and 2014 and the six months ended June 30, 2015, respectively. As of June 30, 2015, we had an accumulated deficit of $6.1 million. We have financed our operations primarily through private placements of our preferred stock and convertible debt securities. We have devoted substantially all of our financial resources and efforts on research and development, including clinical development of gemcabene. We expect that it will be a number of years, if ever, before we have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increased operating losses for the foreseeable future.

To become and remain profitable, we must develop and eventually commercialize a product with market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials, obtaining regulatory approval for a product candidate, manufacturing, marketing and selling any drug for which we may obtain regulatory approval and satisfying any post-marketing requirements. We are in the early stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability.

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 the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, for the fiscal year ended December 31, 2014, our independent registered public accounting firm has issued its report on our financial statements and has expressed substantial doubt about our ability to continue as a going concern. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until and unless the FDA or other applicable regulatory authorities approve gemcabene and we successfully commercialize gemcabene. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. Uncertainty surrounding our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers, contractors and employees.

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Although we believe that the net proceeds from this offering, together with cash on hand, will be sufficient to fund our operations for at least the next 18 months, we will need to raise additional capital to continue to fund the further development of gemcabene and our operations. Our future capital requirements may be substantial and will depend on many factors including:

- the scope, size, rate of progress, results and costs of researching and developing gemcabene and initiating and completing our preclinical studies and clinical trials;
- the cost, timing and outcome of our efforts to obtain marketing approval for gemcabene in the United States and other countries, including to fund the preparation and filing of an NDA with the FDA for gemcabene and to satisfy related FDA requirements and regulatory requirements in other countries;
- the number and characteristics of any additional product candidates we develop or acquire, if any;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the timing and amount of milestone and royalty payments;
- the amount of revenue, if any, from commercial sales, should any product candidate receive marketing approval;
- the costs associated with commercializing gemcabene or any future product candidates, if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell gemcabene or any future product candidates;
- the cost of manufacturing gemcabene or any future product candidates and any product we successfully commercialize; and
- the costs associated with general corporate activities, such as the cost of filing, prosecuting and enforcing patent claims.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval and commercialization of gemcabene and any future product candidates. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are unavailable to us on a timely basis, or at all, we may not be able to continue the development of gemcabene or any future product candidate, or commercialize gemcabene or any future product candidate, if approved, unless we find a strategic partner.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings as well as potential strategic collaborations and licensing arrangements. We do not have any committed external source of funds.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing or preferred equity 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 raise funds through strategic collaborations or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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 prefer to develop and market ourselves. This may reduce the value of our common stock.

In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. Pursuant to our 2015 Plan, our management is authorized to grant stock options to our employees, directors and consultants. The aggregate number of shares of our common stock that may initially be issued pursuant to stock awards under the 2015 Plan after the closing of this offering is shares. The number of shares of our common stock reserved for issuance under the 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors.

To the extent these outstanding options are ultimately exercised or the number of shares available for future grant each year are increased, investors purchasing common stock in this offering will sustain further dilution. See "Dilution" for a more detailed description of the dilution to new investors in the offering.

Risks Related to Government Regulation

Gemcabene is subject to a partial clinical hold with respect to clinical trials of longer than six months in duration, which may lead to a significant delay in the commencement of long term clinical trials by us or the failure of gemcabene to obtain marketing approval.

In 2004, the FDA determined that gemcabene was a potential peroxisome proliferator-activated receptor (PPAR) agonist. As a result, the FDA imposed a partial clinical hold, which restricts us from conducting clinical trials for gemcabene beyond six months in duration, and requires us to conduct two-year rat and mouse carcinogenicity studies before conducting trials of longer than six months. The FDA has issued these notices to all sponsors of product candidates with PPAR properties based on preclinical studies. We plan to complete our two-year rat and mouse carcinogenicity studies by the end of 2017, with draft reports issued soon after. Clinical trials may be delayed due to these clinical restrictions and additional oversight by the FDA. For example, if the results of the two-year rat and mouse carcinogenicity studies do not address FDA concerns related to the partial clinical hold, our Phase 3 long term safety exposure registration trials of longer than six months could be delayed. Also, the findings in the carcinogenicity studies could impact the NDA review, and, if approved, labeling and use of gemcabene.

Even if we receive marketing approval for gemcabene or any product candidate we may pursue in the future in the United States, we may never receive regulatory approval to market such product candidate outside of the United States.

In addition to the United States, we intend to seek regulatory approval to market gemcabene in Canada and Europe and potentially other markets. If we pursue additional product candidates in the future, we may seek regulatory approval of such product candidates outside the United States. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of these other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market gemcabene or any future product candidate in such foreign markets. Any such impairment would reduce the size of our potential market, which could have an adverse impact on our business, results of operations and prospects.

Even if we obtain marketing approval for gemcabene or any product candidate we may pursue in the future, such product candidate could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or experience unanticipated problems with a product candidate following approval.

Any product candidate for which we, or our future collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such drug, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could include requirements for a restricted distribution system.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product candidate. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our future collaborators, do not market a product candidate for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label promotion. Violation of the Federal Food, Drug, and Cosmetic Act (FDC Act) and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown AEs or other problems with our product candidate or its manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- litigation involving patients taking our drug;
- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product recall or public notification or medical product safety alerts to healthcare professionals;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of drugs;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

We may seek to avail ourselves of mechanisms to expedite the development or approval of gemcabene or any other product candidate we may pursue in the future, such as fast track designation, but such mechanisms may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track designation, priority review, or accelerated approval for gemcabene or any other product candidate we may pursue in the future. For example, if a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if we believe a particular product candidate is eligible for any such mechanism, we cannot assure you that the FDA would decide to grant it. Even if we do obtain fast track or priority review designation or pursue an accelerated approval pathway, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that a product candidate will receive marketing approval.

Depending on the results of our Phase 2b clinical trials, we may seek a breakthrough therapy designation for gemcabene or any other product candidate we may pursue in the future. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that are designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. We cannot be sure that our evaluation of a product candidate as qualifying for breakthrough therapy designation will meet the FDA's requirements. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Recently-enacted and future legislation may increase the difficulty and cost for us and our future collaborators to obtain marketing approval of our product candidate and affect its pricing.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of a product candidate, restrict or regulate post-approval activities and affect our ability, or the ability of our future collaborators, to profitably sell any drug for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and cause downward pressure on the price that we, or our future collaborators, may receive for any approved drug.

For example, 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 (collectively, the PPACA). This is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, improve healthcare quality, enhance remedies against fraud and abuse, add new transparency

requirements for certain components of the health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the PPACA of importance to gemcabene and any future product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- 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;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidate for which marketing approval is obtained. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of a product candidate, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and our future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of a drug, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available

therapies. If reimbursement of our drug is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidate 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 market, sell and distribute any product candidate for which we obtain marketing approval. Restrictions and obligations under applicable federal and state healthcare laws and regulations include the following:

- § the federal Anti-Kickback Statute 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, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- § the federal false claims and civil monetary penalties laws, including the civil False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for 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 (HIPAA) imposes criminal and civil liability for, among other things, executing 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, also imposes obligations, including mandatory contractual terms, on certain people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- § the federal Physician Payments Sunshine Act under the PPACA requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services within the U.S. Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- § analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and 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 physicians and other health care providers or marketing expenditures. Certain state and foreign laws also govern the privacy and security of health information in ways that differ from each other and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, 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 is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Our violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States 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. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and 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 be ineffective in controlling unknown or

unmanaged risks or losses or in protecting us from governmental 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 significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as gemcabene, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for gemcabene or any future product candidate for a certain indication, physicians may nevertheless prescribe gemcabene or such future product candidate to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of gemcabene or any future product candidate, if approved, we could become subject to significant liability, which would adversely affect our business and financial condition.

Risks Related to the Commercialization of Gemcabene or Any Future Product Candidate

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We expect to face competition with respect to gemcabene, if approved, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions and government agencies worldwide. The lipid-lowering therapies market is highly competitive and dynamic and dominated by the sale of statin treatments including the cheaper generic versions of statins. Our success will depend, in part, on our ability to obtain a share of the market for our planned indications. Other pharmaceutical companies may develop lipid-lowering therapies for the same indications that compete with gemcabene, if approved, that do not infringe the claims of our patents, pending patent applications or other proprietary rights which could adversely affect our business and results of operations.

Lipid-lowering therapies currently on the market that would compete with gemcabene, if approved, include the following:

- § statins, such as Crestor marketed by AstraZeneca, Zocor marketed by Merck & Co., Inc. and Lipitor marketed by Pfizer and their generic versions;
- § cholesterol absorption inhibitors, such as Zetia, marketed by Merck & Co., Inc.;
- § apoB antisense Kynamro marketed by Genzyme Corporation, a Sanofi company, and MTTP inhibitor Juxtapid marketed by Aegerion Pharmaceuticals, Inc.;
- § combination therapies, such as Vytorin and Liptruzet, both marketed by Merck & Co., Inc.;
- § other lipid-lowering monotherapies, including: fibrates, such as TriCor and Trilipix, both marketed by Abbott Laboratories; niacin, such as Niaspan marketed by AbbVie Inc.; bile acid sequestrants, such as Welchol, marketed by Daiichi Sankyo Inc.; combination therapies, such as Advicor and Simcor, both of which are marketed by AbbVie Inc.; and their generic version of these drugs;

- prescription fish oils, such as Lovaza marketed by GlaxoSmithKline, Epanova marketed by AstraZeneca and Vascepa marketed by Amarin Corporation plc; and

- PCSK9 inhibitors, such as Praluent, developed by Sanofi-Aventis U.S. LLC, and Regeneron Pharmaceuticals, Inc. and Repatha marketed by Amgen Inc.

Several other pharmaceutical companies have other lipid-lowering therapies in development that may be approved for marketing in the United States or outside of the United States. Based on publicly available information, we believe the current therapies in development that would compete with gemcabene include:

- for HoFH, MBX-8025 developed by CymaBay Therapeutics, Inc. and RGEN-1500 being developed by Regeneron Pharmaceuticals, Inc.;

- for HeFH and ASCVD, drugs include: oral cholesteryl ester transfer protein inhibitors, such as anacetrapib being developed by Merck & Co., Inc. and evacetrapib being developed by Eli Lilly and Company; ATP citrate lyase inhibitor, ETC-1002 developed by current Esperion; and PCSK9 inhibitors, such as ALN-PCS02 being developed by The Medicines Company and Alnylam Pharmaceuticals, Inc. and bococizumab being developed by Pfizer; and

- for SHTG, ISIS-APOCIII antisense being developed by Isis Pharmaceuticals, Inc.

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater name recognition, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. 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 registration for clinical trials and entering into strategic transactions, as well as in acquiring technologies complementary to, or necessary for, our programs.

We lack experience commercializing products, which may have an adverse effect on our business.

If gemcabene or any product candidate we may pursue in the future receives marketing approval, we will need to transition from a company with a development focus to a company capable of supporting commercial activities, and we may not be successful in making that transition. We have never filed an NDA, and have not yet demonstrated an ability to obtain marketing approval for, or to commercialize, any product candidate. As a result, our clinical development and regulatory approval process, and our ability to successfully commercialize any approved products, may involve more inherent risk, take longer, and cost more than it would if we were a company with experience obtaining marketing approval for and commercializing a product candidate.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market gemcabene, if approved, or any other product candidate we may pursue, we may not be successful in commercializing such product candidate if and when approved.

We do not have a global sales or marketing infrastructure and have no capabilities in place at the present time for the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource part or all of these functions to other third parties.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize gemcabene or any future product candidate on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidate;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell a product that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market any product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market a drug effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing gemcabene or any future product candidate.

Even if gemcabene or any future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if gemcabene or any future product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If such product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of a product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- any restrictions on the use of our product together with other medications;
- interactions of our product with other medicines patients are taking;
- inability of certain types of patients to take our product;
- demonstrated ability to treat patients and, if required by any applicable regulatory authority in connection with the approval for target indications, to provide patients with incremental cardiovascular disease benefits, as compared with other available therapies;
- the relative convenience and ease of administration of gemcabene, including as compared with other treatments available for approved indications;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the labeling approved by the FDA;

- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness through marketing efforts;
- guidelines and recommendations of organizations involved in research, treatment and prevention of various diseases that may advocate for alternative therapies;
- our ability to obtain sufficient third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- physicians or patients may be reluctant to switch from existing therapies even if potentially more effective, safe or convenient.

If the FDA or a comparable foreign regulatory authority approves generic versions of gemcabene or any future product candidates that receive marketing approval, or such authorities do not grant our product candidates appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications (ANDAs) in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDC Act provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity (NCE). Specifically, in cases where such 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 that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug. It is unclear whether the FDA will treat the active ingredients in our product candidates as NCEs and, therefore, afford them five years of NCE data exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, it may nonetheless be eligible for three years of exclusivity, which means that the FDA may approve generic versions of such product three years after its date of approval. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that gemcabene or any future product candidates may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in any such product candidate.

Even if we are able to commercialize gemcabene or any future product candidate, the profitability of such product candidate will likely depend in significant part on third-party reimbursement practices, which, if unfavorable, would harm our business.

Our ability to commercialize a drug successfully will depend in part on the extent to which coverage and adequate reimbursement will be available from government health administration authorities, private health

insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, whether the level of reimbursement will be adequate. Assuming we obtain coverage for gemcabene, if approved, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use a product candidate, if approved, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which a product candidate is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for a new product, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidate in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with gemcabene or any future product candidate during product testing, manufacturing, marketing or sale. For example, we may be sued on allegations that a product candidate caused injury or that the product is otherwise unsuitable. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot

successfully defend ourselves against claims that our product candidate caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we are developing;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- increased FDA warnings on product labels;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- distraction of management's attention from our primary business;
- loss of revenue; and
- the inability to commercialize any product candidate that we may develop.

We do not yet have product liability or clinical trial insurance coverage, and any coverage that we do obtain may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand clinical trials and if we successfully commercialize gemcabene or any other product candidate we may pursue in the future. Insurance coverage is increasingly expensive, and we may not be able to obtain product liability insurance on commercially reasonable terms or in an amount adequate to satisfy any liability that may arise.

If we 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 have an adverse effect on the success of our business.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by ourselves and our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could adversely affect our operating results.

We may face competition for gemcabene, if approved, from cheaper lipid-lowering therapies sourced from foreign countries that have placed price controls on pharmaceutical products. The Medicare Modernization Act contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has so far declined to approve a reimportation plan. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any product we may develop and adversely affect our future revenues and prospects for profitability.

Risks Related to our Dependence on Third Parties

We will be unable to directly control all aspects of our clinical trials due to our reliance on clinical research organizations (CROs) and other third parties that assist us in conducting clinical trials.

We will rely on CROs to conduct our preclinical studies and clinical trials for any product candidate, including our Phase 2b and Phase 3 trials for gemcabene. As a result, we will have limited control over the conduct, timing and completion of these clinical trials and the management of data developed through the clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control.

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. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

Problems with the timeliness or quality of the work of any CRO may lead us to seek to terminate our relationship with any such CRO and use an alternative service provider. Making this change may be costly and may delay our clinical trials, and contractual restrictions may make such a change difficult or impossible to effect. If we must replace any CRO that is conducting our clinical trials, our clinical trials may have to be suspended until we find another CRO that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of gemcabene or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that any CRO on which we may rely will offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our clinical trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of gemcabene and preclude our ability to commercialize gemcabene, thereby limiting or preventing our ability to generate revenue from its sales.

We rely completely on third parties to supply and manufacture our preclinical and clinical drug supplies for gemcabene, and we intend to rely on third parties to produce commercial supplies of gemcabene and preclinical, clinical and commercial supplies of any future product candidate.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of gemcabene, or any future product candidates, for use in the conduct of our preclinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The process of manufacturing drug products is complex, highly regulated and subject to several risks. For example, the facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient (or drug substance) and final drug product for gemcabene, or any future product candidates, must be inspected by the FDA and other comparable foreign regulatory agencies in connection with our submission of an NDA or relevant foreign regulatory submission to the applicable regulatory agency. In addition, the manufacturing of drug substance or product is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Moreover, the manufacturing facilities in

which gemcabene or any future product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures or other factors.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with current good manufacturing practices (cGMP) for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, we will not be able to secure and/or maintain regulatory approval for our products. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of gemcabene or any future product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market gemcabene or such future product candidates. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory and sourcing risks for the production of such materials and products. To the extent practicable, we attempt to identify more than one supplier, but some raw materials are available only from a single source or only one supplier has been identified, even in instances where multiple sources exist.

We have relied upon third-party manufacturers for the manufacture of our product candidate for preclinical and clinical testing purposes and intend to continue to do so in the future, including for commercial purposes. If our third party manufacturers are unable to supply drug substance and/or drug product on a commercial basis, we may not be able to successfully produce and market gemcabene, if approved, or could be delayed in doing so. For instance, we rely on one supplier for the drug substance for gemcabene. The manufacturer of the drug substance for gemcabene has manufactured batches of the drug substance that will serve as the validation batches that will be reviewed by the FDA in connection with its review of the NDA for gemcabene and as the supply of gemcabene, if approved and successfully launched commercially. If there is any delay or problem with the manufacture of these batches of drug substance or if there is a delay in producing finished product from these batches, the approval of gemcabene may be delayed or any potential launch of gemcabene may be adversely affected. We will rely on comparison of product specifications (identity, strength, quality, potency) to demonstrate equivalence of the current drug substance and/or drug product to the drug substance and/or drug product used in previously completed preclinical and clinical testing. If we are unable to demonstrate such equivalence, we may be required to conduct additional preclinical and/or clinical testing of our product candidate.

These and other problems with any manufacturer may lead us to seek to terminate our relationship with any such manufacturer and use an alternative manufacturer. Making this change may be costly, time consuming and difficult to effectuate, and may delay our research and development activities. If we must replace any manufacturer, our research and development activities may have to be suspended until we find another manufacturer that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the development and commercialization of gemcabene or any future product candidate.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to gemcabene and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. Our likely collaborators include large and mid-size pharmaceutical companies,

regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of gemcabene or any future product candidate. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Collaborations involving gemcabene or any future product candidate pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of any such product candidate;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- the results of collaborators' preclinical or clinical studies could harm or impair other development programs;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers;
- collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and

- collaborators may be unable to obtain the necessary marketing approvals.

If future collaboration partners fail to develop or effectively commercialize gemcabene or any future product candidate for any of these reasons, such product candidate may not be approved for sale and our sales of such product candidate, if approved, may be limited, which would have an adverse effect on our operating results and financial condition.

If we are not able to establish new collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

We face significant competition in attracting collaborators. Whether we reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors related to the associated product candidate. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Much of the potential revenue from future collaborations may consist of contingent payments, such as payments for achieving regulatory milestones or royalties payable on sales of our product candidate, if approved. The milestone and royalty revenue that we may receive under these collaborations will depend upon our collaborators' ability to successfully develop, introduce, market and sell new our product candidate, if approved. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations related to our product candidate, which could reduce the milestone and royalty revenue received, if any.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring it to market and generate product revenue.

Risks Related to our Intellectual Property

If we are unable to adequately protect our proprietary technology or maintain issued patents sufficient to protect gemcabene or any future product candidate, others could compete against us more directly, which would have an adverse impact on our business, results of operations, financial condition and prospects.

Our commercial success will depend in part on our success obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors

may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We licensed patents relating to our current product candidate, gemcabene, from Pfizer. Pursuant to the license agreement, we are responsible for filing, prosecuting and maintaining the patent rights in Pfizer's name at our own cost and expense. In connection with this obligation, we are granted the first right to control the enforcement of the license patents against any third-party infringement actions. Risks related to our Pfizer license are discussed elsewhere in this "Risk Factors" section under "*We depend on intellectual property licensed from Pfizer for gemcabene, and the termination of this license would harm our business.*" The termination of this license could result in the loss of significant rights, which would harm our business.

As of August 31, 2015, our patent estate, including patents we own or license from third parties, on a worldwide basis, included four issued U.S. patents and three pending U.S. patent applications and 20 issued patents in foreign jurisdictions including Canada, France, Germany, Great Britain, Ireland, Italy, Mexico and Spain and 15 pending patent applications in foreign jurisdictions including Australia, Canada, China, Europe, Hong Kong, Japan and Mexico. Our worldwide patents and pending applications all relate to our product candidate, gemcabene. Our patents claiming the gemcabene composition of matter generically, which were in-licensed from Pfizer, have all expired; however, our clinical formulation comprises a specific calcium salt crystal form of gemcabene, which form is claimed in US Patent No. 6,861,555. This patent, which was in-licensed from Pfizer, is expected to expire in 2021, and may be eligible for a patent term extension period of up to five years. Our current patent estate includes four patent families that have claims directed to methods of treatment using gemcabene. These patent families include, for example, U.S. patent 8,557,835, licensed from Pfizer that has claims directed to using a statin-gemcabene combination for treating hyperlipidemia, angina pectoris and atherosclerosis. U.S. patent 8,557,835 is expected to expire in 2021, absent any patent term extension, and corresponding foreign patents are expected to expire in 2018, absent any adjustment or extension. Additionally, U.S. patent number 8,846,761 and U.S. patent application number 14/370,722, are owned by us. U.S. patent number 8,846,761 is directed to methods of decreasing a subject's risk for developing pancreatitis by administering gemcabene and is expected to expire in 2032, absent any patent term extension. Any foreign patent in this family that may issue is expected to expire in 2031, absent any patent term extension. U.S. patent application number 14/370,722, is directed to methods of decreasing a patient's risk for developing coronary heart disease or preventing, delaying or reducing the severity of a secondary cardiovascular event by administering gemcabene with a statin. Related patent applications are pending in foreign jurisdictions including Australia, Canada, China, Europe, Japan and Mexico. Any patent that may issue in this family, absent any patent term adjustment or extension, is expected to expire in 2033.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will 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. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

We cannot assure you that any of our patents have, or that any of our pending patent applications will mature into issued patents that will include, claims with a scope sufficient to protect gemcabene or any future product candidate. Others have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain

cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, *ex parte* reexamination, or *inter partes* review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, or comparable proceedings lodged in various national and regional patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, opposition, post-grant review, *inter partes* review, supplemental examination or revocation proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize gemcabene.

Furthermore, the issuance of a patent, while presumed valid, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of any technical knowledge or trade secrets by consultants, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If, in any proceeding, a court invalidated or found unenforceable our patents covering gemcabene or any future product candidate, our financial position and results of operations would be adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered gemcabene or any future product candidate, our financial position and results of operations would also be adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect gemcabene;
- any of our pending patent applications will result in issued patents;
- we will be able to successfully commercialize gemcabene or any future product candidate, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be valid and enforceable;

- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- that our commercial activities or products will not infringe upon the patents of others.

Patents have a limited lifespan. The natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the extensive period of time between patent filing and regulatory approval for a product candidate, the time during which we can market a product candidate under patent protection is limited, and our patent may expire before we obtain such approval. Without patent protection for gemcabene or any future product candidates, we may be open to competition from generic versions of our product candidates, which may affect the profitability of our product candidates.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidate, our business may be materially harmed.

Depending upon the timing, duration of regulatory review, and date of FDA marketing approval of gemcabene or any future product candidate, if any, one of our U.S. patents may be eligible for patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act provides for a patent restoration term of up to five years as compensation for the time the product is under FDA regulatory review (patent term extension). The duration of patent term extension is calculated based on the time spent in the regulatory review process. Our basic U.S. composition of matter patent for gemcabene has expired. We plan to seek patent term extension for one of our patents related to gemcabene. However, we may not be granted an extension because of, for example, failing to apply within the applicable deadline, expiration of relevant patents prior to obtaining approval, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded 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, our revenue could be reduced, possibly materially.

In addition, we believe that gemcabene is a new chemical entity in the United States and may be eligible for data exclusivity under the Hatch-Waxman Act. A single-ingredient drug can be classified as a new chemical entity if the FDA has not previously approved any other new drug containing the same active ingredient. Under sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the FDCA, as amended, a new chemical entity that is granted marketing approval may, even in the absence of patent protections, be eligible for five years of data exclusivity in the United States following marketing approval. During the data exclusivity period, if granted, the FDA is precluded from approving 505(b)(2) applications or abbreviated new drug applications submitted by another company that references the FDA's findings of safety and efficacy for the approved NDA. 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 reviewing a generic application for eight years, after which generic marketing authorization can be approved but the generic drug may not be marketed during the two-year marketing exclusivity period. However, gemcabene may not be considered to be a new chemical entity for these purposes or be entitled to the period of data exclusivity. If we are not able to gain or exploit the period of data exclusivity, we may face significant competitive threats to our commercialization of gemcabene from other manufacturers, including the manufacturers of generic alternatives. Further, even if our compound is considered to be a new chemical entity and we are able to gain the prescribed period of data exclusivity, another company nevertheless could gain marketing approval for the same compound if they independently generate preclinical and clinical data and get market approval through the NDA process without benefit of our data.

If we fail to maintain orphan drug exclusivity for gemcabene for HoFH, we will have to rely on data and marketing exclusivity for HoFH that is not based on an orphan drug designation, if any, and on our intellectual property rights.

As part of our business strategy, in the United States we have obtained orphan drug designation for gemcabene for the treatment of HoFH. We intend to submit an application to the FDA for orphan drug designation for gemcabene for the treatment of severe hypertriglyceridemia above 750 mg/dL. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000 in the United States.

In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA, to market the same drug for the same orphan indication, except in very limited circumstances. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active pharmaceutical ingredient (API) and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The EMA grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. Orphan drug designation from the EMA provides ten years of marketing exclusivity following drug approval, subject to reduction to six years if the designation criteria are no longer met.

Even if we are able to obtain and maintain orphan drug exclusivity for gemcabene for HoFH, the designation may not effectively protect it from competition for HoFH because different drugs can be approved for the same condition. Moreover, even with an orphan drug designation, the FDA can subsequently approve a different formulation of the same API for the same condition if the FDA concludes that the later formulation of the API is safer, more effective or makes a major contribution to patient care.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect gemcabene and any product candidate we may pursue in the future.

The United States has enacted, and is currently implementing the America Invents Act (AIA) of 2011, wide-ranging patent reform legislation.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. Patent and Trademark Office (USPTO) after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO

proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I)*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Coropration Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening 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 decisions by the U.S. Congress, the federal courts, and the USPTO, 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.

We may not be able to protect or practice our intellectual property rights throughout the world.

In jurisdictions where we have not obtained patent protection, competitors may use our intellectual property to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the U.S. Competitor products may compete with gemcabene, if approved, or any future product candidate in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to pharmaceuticals. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we, or our licensors, encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, or any of our licensors, are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

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

Competitors may infringe our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put

one or more of our patents at risk of being invalidated or interpreted narrowly. 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 this type of litigation. 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.

Litigation proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

In addition, there could 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 have a substantial adverse effect on the price of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell gemcabene and any other product candidate we may pursue in the future and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our medicines and technology, including interference or derivation proceedings, post-grant reviews, inter partes reviews, or other procedures before the USPTO or other similar procedures in foreign jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our medicines and technology. 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 and other third parties access to the same technologies licensed to us. We could be forced, including by court order, to cease developing and commercializing the infringing technology or medicine. In addition, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing a product candidate or force us to cease some of our business operations, which could harm our business. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

The cost to us of any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial and may result in substantial costs and distraction of our management and other employees. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

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

Our employees and consultants have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or

otherwise used or disclosed trade secrets or other proprietary information or intellectual property of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize gemcabene, which would adversely affect our commercial development efforts.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of any product we may pursue could be significantly diminished.

We may rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to trade secrets.

Moreover, because we acquired certain rights to gemcabene from Pfizer, we must rely on Pfizer's practices, and those of its predecessors, with regard to parties that may have had access to trade secrets related thereto. Any party with whom they or 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. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, 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 or other third-party, our competitive position would be harmed.

We have filed U.S. applications for certain of our trademarks, but we have not yet obtained registration of any of our trademarks.

We have filed U.S. applications for three trademarks, "Gemphire", the Gemphire logo and "Advancing a class on top of statins", but we have not yet obtained registration of any of our trademarks in the United States or other countries. If we do not secure and maintain registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could affect our business. We have also not yet registered trademarks for any product candidate in any jurisdiction. When we file trademark applications for a product candidate, those applications may not be allowed for registration, and registered trademarks may not be obtained, maintained or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able 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.

In addition, any proprietary name we propose to use with gemcabene or any future product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed drug names, including an evaluation of potential for confusion with other drug names. If the FDA objects to any proposed proprietary

drug name for any product candidate, we may be required to expend significant additional resources in an effort to identify a suitable substitute proprietary drug name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we register any of our trademarks, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to infringe on other marks. 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. 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.

Obtaining and maintaining our patent protection 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 noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment or other provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

We are dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on our management, scientific and medical personnel, including Dr. Charles L. Bisgaier, our co-founder, Chairman of our board of directors and Chief Scientific Officer, and Mina Sooch, our President, Chief Executive Officer, Treasurer and director. We have entered into employment agreements with Dr. Bisgaier and Ms. Sooch, but any employee may terminate his or her employment with us. The loss of the services of either Dr. Bisgaier or Ms. Sooch, any of our executive officers, other key employees or consultants and other scientific and medical advisors in the foreseeable future, might impede the achievement of our research, development and commercialization objectives. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and business and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical trials may also make it more challenging to recruit and retain qualified scientific personnel.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of August 31, 2015, we have eight full-time employees, and we expect to increase our number of employees and the scope of our operations as we further the clinical development of gemcabene and become a public company. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and

continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of gemcabene. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize gemcabene or any future product candidate, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

A variety of risks associated with operating internationally for us and our collaborators could adversely affect our business.

In addition to our U.S. operations, we may pursue international operations in the future and would face risks associated with such global operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax and labor conditions, which could harm our business. We are also conducting and in the future plan to continue to conduct clinical trials outside of the United States. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for gemcabene or any other product candidate;
- different medical practices and customs affecting acceptance of gemcabene, if approved, or any other approved product in the marketplace;
- language barriers;
- the interpretation of contractual provisions governed by foreign law in the event of a contract dispute;
- difficulties in staffing and managing foreign operations, and an inability to control commercial or other activities where we are relying on third parties;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practice Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capability abroad;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

Our business and operations would suffer in the event of system failures or unplanned events.

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future 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 the further development and commercialization of our product candidates could be delayed.

Furthermore, any unplanned event, such as flood, fire, explosion, tornadoes, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize the facilities, may have an adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations.

Risks Related to our Common Stock and this Offering

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 trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- adverse results or delays in preclinical studies, clinical trials, regulatory decisions or the development status of gemcabene or any product candidates we may pursue in the future;
- decisions to initiate a clinical trial, not initiate a clinical trial, or terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for gemcabene;
- changes in applicable laws, rules or regulations;
- disputes with Pfizer regarding our licensed rights to gemcabene;
- adverse developments concerning our manufacturers, suppliers, collaborators and other third parties;
- our failure to commercialize gemcabene or any product candidates we may pursue in the future;
- the success of competitive drugs;
- additions or departures of key scientific or management personnel;
- unanticipated safety concerns related to the use of gemcabene or any product candidates we may pursue in the future;
- our announcements or our competitor's announcements regarding new products, enhancements, significant contracts, acquisitions or strategic partnerships and investments;
- changes in the structure of healthcare payment systems;
- the size and growth of our target markets;
- our failure, or companies perceived to be similar to us, to meet external expectations or management guidance;
- fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;

- publication of research reports about us or our industry, recommendations, earning results or estimates or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in general economic, political and market conditions in any of the regions in which we conduct our business;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders or our incurrence of additional debt;
- trading volume of our common stock;
- changes in accounting practices and ineffectiveness of our internal controls;
- disputes, litigation or developments relating to proprietary rights;
- timing of milestones and royalty payments; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, NASDAQ, and the stock of biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition, the initial public offering price for our common stock will be determined through our negotiations with the underwriters, and may not bear any relationship to the market price at which our common stock will trade after this offering or to any other established criteria of the value of our business. If the market price of our common stock after this offering does not exceed the initial public offering price or declines, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Provisions in our 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.

Provisions in our corporate charter and our bylaws that will become effective upon the closing of this offering 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 could also 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 preferred stock may include rights superior to the rights of the holders of common stock, and which could be used to institute a shareholder 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 two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or 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.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. As a result, investors purchasing common stock in this offering will suffer immediate and substantial dilution in the net tangible book value of the common stock purchased. Assuming an initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover of this prospectus, purchasers of common stock in this offering will experience immediate dilution of approximately $ per share. In addition, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since inception but will only own approximately % of the shares of common stock outstanding. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering there has been no public market for shares of our common stock. Although we plan to apply to have our common stock listed on NASDAQ, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease.

Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, 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 and trading volume to decline.

Our executive officers, directors, principal stockholders and their affiliates will continue to exercise significant control over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of June 30, 2015, our officers, directors, five percent or greater stockholders and their respective affiliates directly or indirectly held in the aggregate approximately 87.4% of our outstanding voting stock and, immediately following the closing of this offering, disregarding any shares of common stock that they purchase in this offering, the existing holdings of our officers, directors, five percent or greater stockholders and their respective affiliates will represent beneficial ownership, in the aggregate, of approximately % of our outstanding common stock, assuming no exercise of the underwriters' option to acquire additional common stock in this offering. The foregoing discussion assumes that no shares of common stock are purchased by our officers, directors, five percent or greater stockholders and their respective affiliates pursuant to the directed share program or otherwise in this offering.

These stockholders, if they act together, will be able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors, amendments of our organizational documents, and any merger, consolidation, sale of all or substantially all of our assets or other major corporate transaction. These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests, with respect to their common stock, that are different from those of investors in this offering. In addition, this concentration of ownership might adversely affect the market price of our common stock, have the effect of delaying, deferring or preventing a change of control of our company, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

For more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates see "Principal Stockholders."

We have broad discretion in the use of the net proceeds from this offering, and we may use the net proceeds ineffectively, or may allocate them in ways that you and other stockholders may not approve.

We currently intend to use the proceeds from this offering to fund development costs associated with clinical studies and related operations of our Phase 2b clinical trials of gemcabene for our target indications, our End of Phase 2 (EOP2) meeting with the FDA and preclinical studies and related activities for gemcabene, with the balance for general corporate purposes, including working capital, general administrative costs, potential in-licensing costs and the prosecution and maintenance of our intellectual property. Because of the number and variability of factors that will determine our use of the proceeds from this offering, their ultimate use may vary substantially from their currently intended use. As such, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock. For a further description of our intended use of the proceeds of the offering, see "Use of Proceeds."

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute

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

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a 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. For example, we will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002 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.

Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

After this offering, we will be subject to Section 404 of the Sarbanes-Oxley Act and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report

that we will be required to file with the SEC, Section 404 of the Sarbanes-Oxley Act requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Once we are no longer an "emerging growth company" or, if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. 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, hire additional finance and accounting personnel, 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. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated.

In addition, as a public company we will be required to timely file accurate quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from NASDAQ or other adverse consequences that would materially harm our business.

Other than the dividends on our Series A convertible preferred stock, which may be paid in stock, we do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our capital stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

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 doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. 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. Upon closing of this offering, we will have shares of common stock outstanding. This includes shares that we are selling in this offering (or shares, if the underwriters exercise their option in full), which may be resold in the public market

immediately without restriction, unless purchased by our affiliates. The remaining shares are currently restricted as a result of securities laws or lock-up agreements and will be able to be sold as described in the "Shares Eligible for Future Sale" section of this prospectus.

Moreover, after this offering, holders of an aggregate of approximately shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. See "Description of Capital Stock — Registration Rights."

We also intend to register all the shares of common stock that we may issue under our equity incentive plans. Effective upon the effectiveness of the registration statement of which this prospectus is a part, an aggregate of shares of our common stock will be reserved for future issuance under these plans. Once we register these shares, which we plan to do shortly after the closing of this offering, they can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock. For a more detailed description of sales that may occur in the future, see "Shares Eligible for Future Sale".

Our issuance of the common stock pursuant to this offering might result in an "ownership change" at the time of issuance, which will increase the risk that we could experience an ownership change in the future. Any ownership change would significantly limit our ability to utilize our net operating loss carryforwards and certain other tax attributes.

As of June 30, 2015, we had approximately $2.5 million in U.S. federal and state net operating loss carryforwards, which will begin to expire in 2034 for federal and 2024 for state, that we can use in certain circumstances to offset any future taxable income and thus reduce any federal income tax liability. We also had net tax credit carryforwards of $29,000 available to reduce future tax liabilities, if any, for U.S. federal purposes. Our ability to utilize these net operating losses and tax credit carryforwards to offset future taxable income may be significantly limited if we experience an "ownership change," as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. In general, an ownership change will occur if there is a cumulative change in our ownership by "5-percent shareholders" (as defined in the Code) that exceeds 50 percentage points over a rolling three-year period. A corporation that experiences an ownership change will generally be subject to an annual limitation on the corporation's subsequent use of net operating loss carryovers that arose from pre-ownership change periods and use of losses that are subsequently recognized with respect to assets that had a built-in-loss on the date of the ownership change. The amount of the annual limitation generally equals the value of the corporation immediately before the ownership change multiplied by the long-term tax-exempt interest rate (subject to certain adjustments). To the extent that the limitation in a post-ownership-change year is not fully utilized, the amount of the limitation for the succeeding year will be increased.

We do not expect to experience an ownership change as a result of our issuance of common stock in this offering. Nevertheless, the rules regarding the determination of whether an ownership change exists are complicated and are subject to differing interpretations, and it is possible that such issuances might be treated as resulting in an ownership change. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study. Even if there will be no immediate ownership change as a result of such issuance, the issuance of stock pursuant to this offering will be taken into account in determining the cumulative change in our ownership for Section 382 purposes. As a result, this offering materially increases the risk that we could experience an ownership change in the future. If we experience an ownership change, we may not be able to fully utilize our net operating losses, resulting in additional income taxes and a reduction in our stockholders' equity.

Our amended and restated bylaws will designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws will provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, as amended, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our anticipated timing of regulatory submissions; commencement and completion of preclinical studies and clinical trials, meetings with the FDA and other regulatory authorities; and product approvals for gemcabene or any other product candidates we may pursue in the future;
- the outcome of our Phase 2b and Phase 3 clinical trials of gemcabene and our ability to replicate positive results from a completed clinical trial in a future clinical trial;
- our expected clinical trial designs and regulatory pathways, including any requirements to conduct additional, unplanned clinical trials (such as an outcome trial) before approval;
- our expectations for the attributes of gemcabene or any other product candidate we may pursue in the future, including pharmaceutical properties, efficacy, safety, dosing regimens and cost, as compared to other lipid-lowering therapies;
- our ability to design an efficient development plan;
- our expectation that our existing capital resources and the net proceeds from this offering will be sufficient to enable us to complete our planned Phase 2b clinical trials, commence our Phase 3 registration trials and complete certain preclinical studies;
- our plans to advance the late-stage clinical development of gemcabene across multiple target indications, pursue oral combination opportunities for gemcabene, maximize the global commercial value of gemcabene and leverage the expertise and experience of our management team to evaluate future in-license acquisition opportunities;
- our estimates regarding industry trends and market potential for gemcabene;
- if approved, our ability to maintain regulatory approval of gemcabene and respond and adhere to regulatory requirements;
- our ability to develop and, if approved, successfully commercialize best-in-class products, including gemcabene or any other product candidates we may pursue in the future;
- our ability to enhance brand awareness among key thought leaders and physicians;
- if approved, the rate and degree of market acceptance of gemcabene or any other product candidates we may pursue in the future;
- if approved, our ability to compete with other companies that are, or may be, developing or selling products that may compete with gemcabene;
- reimbursement policies, including any future changes to such policies or related government legislation and our ability to sell gemcabene, if approved;
- regulatory and legal developments in the United States and in foreign countries;
- our ability to obtain and maintain intellectual property protection for gemcabene or any other product candidates we may pursue in the future and not infringe upon the intellectual property of others;
- our ability to fund our working capital requirements;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to, obtain additional financing;

- the ability of any third parties with whom we collaborate for the development and commercialization of gemcabene to successfully perform their assigned functions;
- our ability to retain and recruit key scientific and management personnel;
- our financial performance;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our expected use of the proceeds from this offering.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

STATISTICAL DATA AND MARKET INFORMATION

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size, the incidence of certain medical conditions and other industry data. These data, to the extent they contain estimates or projections, involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in "Risk Factors." These and other factors could cause results to differ materially from those expressed in these publications and reports.

USE OF PROCEEDS

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

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the estimated 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 estimated underwriting discounts and commissions.

Similarly, a 1,000,000 share 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 of $ per share, the mid-point of the estimated price range set forth on the cover of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions.

The principal purposes of this offering are to make significant investments in research and development and clinical activities related to gemcabene and for working capital and other general corporate purposes as well as to establish a public market for our common stock and to facilitate our future access to the public equity markets. We anticipate that we will use the net proceeds of this offering, together with our cash and cash equivalents for the following purposes:

- approximately $ million to fund development costs associated with our Phase 2b clinical trials of gemcabene for our target indications and for costs associated with our planned EOP2 meeting with the FDA;
- approximately $ million to fund development costs associated with preclinical studies and related activities for gemcabene; and
- the balance for general corporate purposes, including working capital, general administrative costs, potential in-licensing costs and the prosecution and maintenance of our intellectual property.

We may also use a portion of the remaining net proceeds to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We expect to have our EOP2 meeting with the FDA in the first half of 2017. Based upon our currently anticipated Phase 2b clinical trials, we believe we will have sufficient resources to initiate our planned Phase 3 registration trials of gemcabene, although we will need to raise additional capital to continue to fund the further development of gemcabene and our other operations. The amount and timing of our actual expenditures will depend upon numerous factors, including our ability to gain access to additional financing and the relative success and cost of our research, preclinical and clinical development programs. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our cash resources sooner than we expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical trials is costly and the timing of progress in these clinical trials is uncertain.

Our expected use of the 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 certainty all of the particular uses for the net proceeds to be received upon the closing of this offering, or the amounts

that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to access additional financing, the relative success and cost of our research, preclinical and clinical development programs, whether we are able to enter into future licensing arrangements and the other factors described under "Risk Factors" in this prospectus. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue clinical trials or preclinical activities if the net proceeds from this offering and any other sources of cash are less than expected.

Pending their use, 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, or hold them as cash.

DIVIDEND POLICY

Immediately prior to the closing of this offering, we intend to issue to our existing holders of Series A convertible preferred stock upon the conversion of their Series A convertible preferred stock into common stock in connection with this offering approximately shares in common stock in accrued dividends (Accrued Dividends).

Other than the Accrued Dividends, we do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2015:

- on an actual basis;
- on a pro forma basis to reflect (1) the conversion of all our outstanding shares of our convertible preferred stock into 2,325,581 shares of common stock immediately prior to the closing of this offering, (2) the issuance of shares of common stock immediately prior to the closing of the offering pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy", (3) the immediate vesting of 2,008,097 shares of restricted stock valued at $56,227 held by certain employees upon the closing of this offering and (4) the filing of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to reflect (1) the pro forma adjustments set forth above and (2) our sale in this offering of shares of common stock at an assumed initial public offering price of $ per share, the mid-point of the estimated 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.

You should read the following table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Description of Capital Stock" and the financial statements and related notes appearing elsewhere in this prospectus.

	As of June 30, 2015		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Cash and cash equivalents	$ 2,189	$	$
Series A convertible preferred stock, $0.001 par value per share; 2,325,581 shares authorized, 2,325,581 shares issued and outstanding, actual; 2,325,581 shares authorized, no shares issued and outstanding, pro forma; no shares authorized, no shares issued and outstanding, pro forma as adjusted	7,651	—	—
Stockholders' (deficit) equity:			
Preferred stock, $0.001 par value per share; no shares authorized, issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value per share; 17,674,419 shares authorized, 11,715,103 shares issued and outstanding, actual; 17,674,419 shares authorized, 14,040,684 shares issued and outstanding, pro forma; and shares authorized, shares issued and outstanding, pro forma as adjusted	12		
Additional paid in capital	—		
Accumulated deficit	(6,104)		
Total stockholders' (deficit) equity	(6,092)		
Total capitalization	$ 1,559	$ 1,559	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization, on a pro forma as adjusted basis, by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, total stockholders' (deficit) equity and total capitalization, on a pro forma as adjusted basis, by approximately $ million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The tables and calculations above are based on 14,040,684 shares of common stock outstanding as of June 30, 2015, and exclude:

- 318,522 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2015 at an exercise price of $0.431 per share;
- 266,600 shares of common stock issuable upon the exercise of stock options granted after June 30, 2015 at an exercise price of $0.68 per share;
- shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan, which will be amended and restated in connection with this offering, and shares of common stock reserved for future issuance under our 2015 Employee Stock Purchase Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under these plans; and
- shares issuable to holders of our convertible bridge notes issued after June 30, 2015 upon conversion thereof.

DILUTION

If you invest in our common stock in this offering, 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 after this offering. Net tangible book value dilution per share to new investors 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.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. Our pro forma net tangible book value as of June 30, 2015 was $ million, or $ per share of common stock. Pro forma net tangible book value gives effect to: (1) the conversion of all our outstanding shares of our convertible preferred stock into 2,325,581 shares of common stock immediately prior to the closing of this offering, (2) the issuance of shares of common stock immediately prior to the closing of the offering pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy", (3) the immediate vesting of 2,008,097 shares of restricted stock valued at $56,227 held by certain employees upon the closing of this offering and (4) the filing of our amended and restated certificate of incorporation immediately prior to the closing of this offering.

After giving effect to: (1) the pro forma adjustments set forth above and (2) the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2015 would have been approximately $ million, or $ per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors purchasing shares in this offering.

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

Assumed initial public offering price per share		$
Pro forma net tangible book value (deficit) per share as of June 30, 2015	$ ( )	
Increase in pro forma net tangible book value per share attributable to investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma as adjusted net tangible book value per share to new investors in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately $ per share and the dilution in pro forma per share to investors participating in this offering by approximately $ 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 the estimated underwriting discounts and commissions.

Similarly, a 1,000,000 share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately $ million and decrease (increase) the dilution in pro forma per share to investors participating in this offering by approximately $ million, assuming the

assumed initial public offering price of $ per share (the mid-point of the estimated price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions.

If the underwriters exercise in full their option to purchase additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value per share after this offering will increase to $ per share, representing an immediate increase in pro forma as adjusted net tangible book value to existing stockholders of $ per share and an immediate decrease of dilution of $ per share to new investors participating in this offering.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2015, the number of shares purchased or to be purchased from us, the total consideration paid or to be paid to us, and the average price per share paid or to be paid to us by existing stockholders and investors participating in this offering at the initial public offering price of $ per share, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENT	
Existing stockholders before this offering		%	$	%	$
Investors participating in this offering					
Total		100.0%	$	100.0%	$

Except as otherwise indicated, the tables and calculations above assume no exercise of the underwriters' over-allotment option. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding after the closing of this offering.

The tables and calculations above are based on the number of shares of our common stock outstanding as of June 30, 2015, and exclude:

- 318,522 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2015 at an exercise price of $0.431 per share;
- 266,600 shares of common stock issuable upon the exercise of stock options granted after June 30, 2015 at an exercise price of $0.68 per share;
- shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan, which will be amended and restated in connection with this offering, and shares of common stock reserved for future issuance under our 2015 Employee Stock Purchase Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under these plans; and
- shares issuable to holders of our convertible bridge notes issued after June 30, 2015 upon conversion thereof.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

SELECTED FINANCIAL DATA

The following selected financial data should be read together with "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements, related notes and other financial information included elsewhere in this prospectus. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

We derived the statements of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2013 and 2014 from our audited financial statements included elsewhere in this prospectus. We derived the statements of operations data for the six months ended June 30, 2014 and 2015 and the balance sheet data as of June 30, 2015 from our unaudited financial statements included elsewhere in this prospectus. The unaudited financial statements have been prepared on the same basis as our audited financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of results to be expected in any future period, and results from any interim period may not necessarily be indicative of the results of a full year or any other period.

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
			(unaudited)	
	(in thousands, except share and per share amounts)			
Statements of Operations Data:				
Operating expenses:				
General and administrative	$ 97	$ 214	$ 48	$ 1,133
Research and development	1	52	42	1,158
Acquired in-process research and development	—	—	—	908
Total operating expenses	98	266	90	3,199
Loss from operations	(98)	(266)	(90)	(3,199)
Interest expense	(13)	(55)	(10)	(690)
Other income (expense)	—	1	—	(1)
Net loss	(111)	(320)	(100)	(3,890)
Adjustment to redemption value on Series A convertible preferred stock	—	—	—	(2,666)
Net loss attributable to common stockholders	$ (111)	$ (320)	$ (100)	$ (6,556)
Net loss per share attributable to common stockholders, basic and diluted[(1)]		$ (0.07)		$ (0.83)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted[(1)]		4,746,648		7,902,438
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]		$		$
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]				

(1) See note 10 to our financial statements appearing elsewhere in this prospectus for further details on the calculation of net loss per share attributable to common stockholders, basic and diluted, and pro forma net loss per share attributable to common stockholders, basic and diluted, and the weighted-average number of shares used in computation of the per share amounts.

	December 31, 2013	December 31, 2014	June 30, 2015 (unaudited)
	(in thousands)		
Balance Sheet Information:			
Cash and cash equivalents	$ 3	$ 317	$ 2,189
Working capital	14	13	12
Total assets	18	348	2,221
Long term debt obligations	246	—	—
Total liabilities	281	878	662
Series A convertible preferred stock	—	—	7,651
Accumulated deficit/members' deficit	(264)	(584)	(6,104)
Total stockholders' deficit/members' deficit	(264)	(530)	(6,092)

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

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease. Dyslipidemia is generally characterized by an elevation of LDL-C, or bad cholesterol, triglycerides, or fat in the blood, or both. We are developing our product candidate gemcabene, a novel, once-daily, oral therapy, for patients who are unable to achieve normal levels of LDL-C or triglycerides with currently approved therapies, primarily statin therapy. Gemcabene's dual mechanism of action is designed to both inhibit the production of fatty acids and cholesterol in the liver and enhance the clearance of VLDLs in the plasma. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in 895 subjects, which we define as healthy volunteers and patients, across 18 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

We are initially pursuing gemcabene in the following four indications as a treatment in addition to maximally tolerated statin therapy for patients who are unable to reach their lipid-lowering goals: HoFH, SHTG, HeFH and ASCVD. We believe we can design an efficient development plan to provide a new treatment alternative for these patients. Furthermore, we believe that gemcabene's potential ability to treat patients in the most severe segment of the dyslipidemia market will enhance brand awareness among key thought leaders and physicians. We are developing gemcabene for HeFH, ASCVD and SHTG given gemcabene's: (1) promising clinical data in these indications; (2) cost-effective manufacturing process; (3) convenient oral dosing; (4) viability as adjunct combination therapy; and (5) large commercial potential. In the first half of 2016, we expect to initiate three Phase 2b trials for gemcabene in HoFH, hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins, and SHTG. Upon completion of our Phase 2b trials, we intend to request an End of Phase 2 (EOP2) meeting with the FDA to reach an agreement on the design of Phase 3 registration trials and long term safety exposure for our target indications. We intend to pursue similar discussions with Canadian and European health authorities.

Our Company was co-founded in November 2008 as a limited liability company under the name Michigan Life Therapeutics, LLC (MLT) by former Pfizer employees, Dr. Charles Bisgaier and Mr. David Lowenschuss, who were responsible for licensing exclusive worldwide rights to gemcabene from Pfizer in April 2011. In October 2014, we incorporated a new entity under the name Gemphire Therapeutics Inc. in Delaware. In November 2014, we entered into a merger agreement with Gemphire whereby MLT was merged with and into Gemphire, with Gemphire as the surviving entity and all outstanding units of membership interest in MLT were exchanged for shares of common stock of Gemphire. The purpose of the merger was to change the jurisdiction of our incorporation from Michigan to Delaware and to convert from a limited liability company to a corporation.

To date, our primary activities have been conducting research and development activities, planning clinical trials, performing business and financial planning, recruiting personnel and raising capital. We do not have any products approved for sale and have not generated any revenue. We do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve gemcabene and we successfully commercialize gemcabene. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings as well as collaborations, strategic alliances and licensing arrangements. To date, we have funded our operations primarily through the issuance of preferred stock and convertible notes, totaling $4.2 million in gross proceeds. Our net losses were $0.1 million, $0.3 million and $3.9 million for the years ended December 31, 2013 and 2014 and for the six months ended June 30, 2015, respectively. As of June 30, 2015, we had an accumulated deficit of $6.1 million. We anticipate that our expenses will increase substantially as we:

- continue clinical trials for gemcabene and for any other product candidate in our future pipeline;
- develop additional product candidates that we identify, in-license or acquire;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- contract to manufacture our product candidates;
- establish on our own or with partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, operational and financial personnel, to execute our business plan;
- add operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- to enable us to operate as a public company.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies, clinical trials and our expenditures on other research and development activities.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. We do not expect to generate revenue unless or until we obtain regulatory approval of and commercialize gemcabene. If we fail to complete the development of gemcabene, or any other product candidate we may pursue in the future, in a timely manner, or fail to obtain regulatory approval, our ability to generate future revenue would be compromised.

Operating Expenses

Our operating expenses are classified into three categories: general and administrative, research and development and acquired in-process research and development.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, including salaries and share-based compensation costs, for personnel in functions not directly associated with research and administrative activities. Other significant costs include legal fees relating to intellectual property and corporate matters and professional fees for accounting and other services. We anticipate that our general and administrative expenses will significantly increase in the future to support our continued research and development activities, potential commercialization of gemcabene, if approved, and any future product candidates we may develop and the increased costs of operating as a public company. These increases will include increased costs related to the hiring of additional personnel and fees for legal and professional services, as well as other public-company related costs.

Research and Development

To date, our research and development expenses have related primarily to the clinical stage development of gemcabene. Research and development expenses consist of costs incurred in performing research and development activities, including compensation for research and development employees, costs associated with preclinical studies and trials, regulatory activities, manufacturing activities to support clinical activities, license fees, nonlegal patent costs, fees paid to external service providers that conduct certain research and development, clinical costs and an allocation of overhead expenses. Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the study or project, and the invoices received from our external service providers. We adjust our accrual as actual costs become known. Research and development activities are central to our business model.

We expect that gemcabene will have higher development costs during its later stages of clinical development, as compared to costs incurred during its earlier stages of development, primarily due to the increased size and duration of the later-stage clinical trials, so we expect our research and development expenses to significantly increase over the next several years as we continue to conduct preclinical studies and clinical trials for gemcabene and potentially develop other product candidates. However, it is difficult to determine with certainty the duration, costs and timing to complete our current or future preclinical programs and clinical trials of gemcabene. The duration, costs and timing of clinical trials and development of gemcabene will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidate;
- arrangements with contract research organizations and other service providers; and
- the efficacy and safety profile of the product candidates.

Acquired In-Process Research and Development

We include costs to acquire or in-license product candidates in acquired in-process research and development expenses. When we acquire the right to develop and commercialize a new product candidate, any up-front payments, or any future milestone payments that relate to the acquisition or licensing of such a right are immediately expensed as acquired in-process research and development in the period in which they are incurred. These costs are immediately expensed provided that the payments do not also represent processes or activities that would constitute a "business" as defined under generally accepted accounting principles in the United States (GAAP), or provided that the product candidate has not achieved regulatory approval for marketing and, and absent obtaining such approval, has no alternative future use. Royalties owed on future sales of any licensed product will be expensed in the period the related revenues are recognized.

Interest Expense

Interest expense consists of interest costs related to promissory notes outstanding as well as interest cost and the underlying premium conversion derivative related to the convertible notes issued by us. Both the promissory and convertible notes had an annual interest rate of 8%. The interest on the promissory notes

compounded on an annual basis while the interest on the convertible notes compounded daily. All of the convertible notes were converted to Series A preferred shares in March 2015.

We expect to earn interest income in future periods from the investment of net proceeds from this offering in interest bearing instruments.

Other Income (Expense)

Other income (expense) relates to foreign currency exchange gains and losses. Foreign currency exchange gains and losses relate to transactions and monetary asset and liability balances denominated in currencies other than the U.S. dollar. Foreign currency gains and losses may continue to fluctuate in the future due to changes in foreign currency exchange rates.

Provision for Income Taxes

Provision for income taxes consists of federal and state income taxes in the United States, as well as deferred income taxes and changes in related valuation allowance reflecting the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Currently, there is no provision for income taxes, as we have incurred operating losses to date, and a full valuation allowance has been provided on the net deferred tax assets as of December 31, 2014 and June 30, 2015.

Results of Operations

The following table summarizes our operating results for the periods indicated:

	Year Ended December 31,			Six Months Ended June 30,		
	2013	2014	Change	2014	2015	Change
			(in thousands)		(unaudited)	
Operating expenses:						
General and administrative	$ 97	$ 214	$ 117	$ 48	$ 1,133	$ 1,085
Research and development	1	52	51	42	1,158	1,116
Acquired in-process research and development	—	—	—	—	908	908
Total operating expenses	98	266	168	90	3,199	3,109
Loss from operations	(98)	(266)	(168)	(90)	(3,199)	(3,109)
Interest expense	(13)	(55)	(42)	(10)	(690)	(680)
Other income (expense)	—	1	1	—	(1)	(1)
Net loss	$ (111)	$ (320)	$ (209)	$ (100)	$ (3,890)	$ (3,790)

Comparison of Years Ended December 31, 2013 and 2014

General and Administrative

General and administrative expenses for the year ended December 31, 2013 were $0.1 million compared to $0.2 million for the year ended December 31, 2014. The $0.1 million increase was primarily attributable to an increase in staffing and consulting services and included $54,000 in share-based compensation expense in 2014. There were no stock grants prior to November 2014, and as such, there was no share-based compensation expense in 2013.

Research and Development

Research and development expenses for the year ended December 31, 2013 were $1,000 compared to $52,000 for the year ended December 31, 2014. The $51,000 increase was primarily attributable to the further development and clinical trial activity of gemcabene.

Interest Expense

Non-cash interest expense for the year ended December 31, 2013 was $13,000 compared to $55,000 for the year ended December 31, 2014. The $42,000 increase in interest expense was primarily related to the issuance of promissory notes, which were exchanged for convertible notes in November 2014, as well as related to the issuance of new convertible notes in December 2014.

Comparison of the Six Months Ended June 30, 2014 and 2015

General and Administrative

General and administrative expenses for the six months ended June 30, 2014 was $48,000 compared to $1.1 million for the six months ended June 30, 2015. The $1.1 million increase was primarily attributable to an increase in staffing and professional services. General and administrative expenses included $87,000 in share-based compensation expense during the six months ended June 30, 2015 versus $0 in the comparable prior year period.

Research and Development

Research and development expenses for the six months ended June 30, 2014 were $42,000 compared to $1.2 million for the six months ended June 30, 2015. The $1.1 million increase was primarily attributable to preclinical studies and manufacturing activities to support clinical advancement of gemcabene and fees paid to external service providers for clinical trial development and regulatory consulting.

Acquired In-process Research and Development

Acquired in-process research and development expenses for the six months ended June 30, 2015 were $0.9 million. There were no acquired in-process research and development expenses during the comparable period in the prior year. The increase was attributable to an equity milestone payment under our license agreement with Pfizer. We issued 2,106,103 shares of common stock to Pfizer and immediately expensed the equity milestone payment in the first quarter of 2015 as acquired in-process research and development expenses at the fair value equivalent of the shares issued in the amount of $0.9 million.

Interest Expense

Non-cash interest expense for the six months ended June 30, 2014 was $10,000 compared to $0.7 million for the six months ended June 30, 2015. The $0.7 million increase was primarily due to the issuance of convertible notes in the first quarter of 2015. All of the convertible notes were converted to Series A preferred shares on March 31, 2015. There were no convertible notes outstanding during the six months ended June 30, 2014.

Liquidity and Capital Resources

Capital Resources

As of December 31, 2014, our principal sources of liquidity consisted of cash and cash equivalents of approximately $0.3 million. As of June 30, 2015, our principal sources of liquidity consisted of cash and cash equivalents of $2.2 million. Our cash and cash equivalents are invested primarily in cash deposits.

We have not generated any revenue, and we anticipate that we will continue to incur losses for the foreseeable future.

We anticipate that our expenses will increase substantially as we:

- continue clinical trials for gemcabene and for any other product candidate in our future pipeline;
- develop additional product candidates that we identify, in-license or acquire;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- contract to manufacture our product candidates;
- establish on our own or with partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, operational and financial personnel, to execute our business plan;
- add operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- to enable us to operate as a public company.

Historical Capital Resources

Our primary source of cash has been proceeds from the issuance of preferred stock and from the issuance of convertible notes and promissory notes. From March 2009 through October 2014, we issued promissory notes for aggregate net proceeds of $0.3 million. The promissory notes compounded at an 8% rate per annum basis and were exchanged for convertible notes on November 1, 2014. From November 2014 through February 2015, we issued convertible notes for aggregate net proceeds of $2.4 million. The convertible notes compounded on a daily basis at an 8% rate per annum and $0.7 million was outstanding as of December 31, 2014. The convertible notes were converted into shares of our Series A preferred stock upon close of the preferred stock financing in March 2015. The conversion equaled 125% of the unpaid principal plus unpaid accrued interest on the convertible notes.

In March 2015, we issued preferred stock for aggregate net proceeds of approximately $1.5 million. The proceeds from the issuances of preferred stock and from the issuances of the convertible and promissory notes have been used to fund our operations.

In addition to our historical sources of cash through June 30, 2015, on July 31, 2015, we entered into a convertible note financing in which we issued 8% convertible notes in an aggregate principal amount of $2.8 million to various investors. By their terms, upon any stock financing resulting in at least $5.0 million of new invested capital, 115% of the outstanding principal, plus accrued interest, under such notes shall convert into shares of the same series of stock issued in such financing at a conversion price equal to the per share price of the stock issued in such financing. In the event that we approve a change of control transaction or firmly underwritten public offering of our common stock prior to the consummation of such a stock financing, the convertible notes are repayable at the election of the holders of a majority of the outstanding principal amount, including a 100% premium on the principal amount if such repayment occurs in connection with a change of control transaction. In the event that a stock financing, change of control or initial public offering has not occurred by July 31, 2016, we are obligated to negotiate the conversion of the convertible notes into a new round of stock.

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
			(unaudited)	
	(in thousands)			
Net cash used in operating activities	$ (109)	$ (195)	$ (40)	$ (1,615)
Net cash used in investing activities	—	—	—	—
Net cash provided by financing activities	108	509	45	3,487
Net (decrease) increase in cash	$ (1)	$ 314	$ 5	$ 1,872

Cash Flow from Operating Activities

For the year ended December 31, 2013, cash used in operating activities totaled $0.1 million, primarily attributable to a net loss of $0.1 million.

For the year ended December 31, 2014, cash used in operating activities of $0.2 million was attributable to a net loss of $0.3 million, partially offset by $108,000 in non-cash expenses and a net change of $17,000 in our net operating assets and liabilities. The non-cash expenses consisted of $54,000 of share-based compensation and non-cash interest of $54,000 related to both the convertible notes and to the premium conversion derivative. The change in operating assets and liabilities was primarily attributable to increases in accrued liabilities associated with our increased operating expenses.

For the six months ended June 30, 2014, cash used in operating activities of $40,000 was attributable to a net loss of $0.1 million, partially offset by non-cash interest of $10,000 related to promissory notes and a net change of $50,000 in our net operating assets and liabilities, primarily attributable to increases in accounts payable and accrued liabilities.

For the six months ended June 30, 2015, cash used in operating activities of $1.6 million was attributable to a net loss of $3.9 million, partially offset by $1.7 million in non-cash expenses and a net change of $0.6 million in our net operating assets and liabilities. The non-cash expenses consist of $0.1 million of share-based compensation, non-cash interest of $0.7 million related to both the convertible notes and to the premium conversion derivative, and $0.9 million related to a non-cash purchase of acquired in-process research and development pursuant to the issuance of common stock. The change in operating assets and liabilities was attributable to increases in accounts payable and accrued liabilities associated with our increased operating expenses.

Cash Flow from Investing Activities

There were no sources or uses of funds from investing activities for all periods presented.

Cash Flow from Financing Activities

Net cash provided by financing activities during the year ended December 31, 2013 consisted of $0.1 million in proceeds from the issuance of promissory notes.

Net cash provided by financing activities during the year ended December 31, 2014 was $0.5 million, consisting of $0.4 million in proceeds from the issuance of convertible notes and $0.1 million in proceeds received from the issuance of promissory notes.

Net cash provided by financing activities was $45,000 and $3.5 million during the six months ended June 30, 2014 and 2015, respectively. Net cash provided by financing activities during the six months ended June 30, 2015 consisted of $1.5 million in proceeds from the issuance of Series A preferred stock

and $2.0 million in proceeds from the issuance of convertible notes. Net cash provided by financing activities during the six months ended June 30, 2014 consisted of $45,000 in proceeds from the issuance of promissory notes.

Liquidity and Capital Resource Requirements

We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve gemcabene and we successfully commercialize gemcabene. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings as well as collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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 raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development, future commercialization efforts, or grant rights to develop and market gemcabene that we would otherwise prefer to develop and market ourselves.

Our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the years ended December 31, 2013 and 2014, noting the existence of substantial doubt about our ability to continue as a going concern. This uncertainty arose from management's review of our results of operations and financial condition and its conclusion that, based on our operating plans, we did not have sufficient existing working capital to sustain operations through December 31, 2015. To continue to fund operations, we will need to raise capital in addition to the net proceeds of this offering. We may obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. Although we believe that the net proceeds from this offering, together with cash on hand, will be sufficient to fund our operations for at least the next 18 months, including our EOP2 meeting with the FDA as well as to commence our Phase 3 registration trials, we will need to raise additional capital to continue to fund the further development of gemcabene and our operations for additional treatment indications and commercialization of gemcabene, if approved. We have based this estimate on assumptions that may prove to be substantially different than we currently anticipate, however, and we could use our cash resources sooner than we expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical trials is costly, and the timing of progress in these clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2014, which represent material expected or contractually committed future obligations.

	Payments Due by Period				
	Less than 1 year	1-3 Years	3-5 Years	More than 5 years	Total
			(in thousands)		
Convertible notes[1]	$ 737	$ —	$ —	$ —	$ 737
Total	$ 737	$ —	$ —	$ —	$ 737

(1) The convertible notes were converted to Series A preferred stock on March 31, 2015.

We lease a facility under a fixed non-cancellable operating lease effective on January 1, 2015 that, as amended, expires on September 30, 2015. Additionally, in the course of our normal operations, we have entered into cancellable purchase commitments with our suppliers for various key research and clinical services and raw materials. The purchase commitments covered by these arrangements are subject to change based on our research and development efforts.

In April 2011, we entered into a license agreement with Pfizer (the Pfizer Agreement) for a worldwide exclusive license to certain patent rights to make, use, sell, offer for sale and import the clinical product candidate gemcabene. In exchange for this license, we agreed to issue shares of our common stock to Pfizer representing 15% of our fully diluted capital at the close of our first arms-length Series A financing, which occurred in March 2015.

We agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first regulatory submission in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene or any product containing gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

We have also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales as specified in the Pfizer Agreement until expiration of the last valid claim of the licensed patent rights, including any patent term extensions or supplemental protection certificates. Under the Pfizer Agreement we are obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

The Pfizer Agreement will expire upon expiration of the last royalty term. Either party may terminate the Pfizer Agreement for the other party's uncured material breach and specified bankruptcy events. Pfizer may terminate the Pfizer Agreement if we or any of our sublicensees challenge the validity, enforceability or ownership of the licensed patents. Additionally, Pfizer may revoke the license if we are unable to adequately commercialize gemcabene by April 2021.

As of June 30, 2015, no obligations were recorded related to the Pfizer Agreement due to the inability to reasonably estimate the timing and outcomes of the gemcabene trials as well as the timing and amounts of future sales of gemcabene, if any.

Upon the issuance of our Series A preferred stock in March 2015, the Series A preferred stockholders effectively receive cumulative accruing dividends at a simple rate of 8% per year on the original issue price of the preferred stock. The dividends are payable upon the earliest to occur of (1) the date determined by the board of directors, (2) the liquidation of the Company (including a deemed liquidation event) or (3) the

conversion or redemption of at least a majority of the outstanding shares of Series A preferred stock. If our board reasonably believes that we are not legally able to pay the dividends in cash at the payment date, or if elected by the majority of the Series A preferred stockholders, the dividends shall be paid in shares of common stock at the conversion price for the Series A preferred stock in effect at that time, which is the original issue price of the Series A preferred stock as adjusted from time to time for any stock dividends, combinations, splits or recapitalizations. Since the dividends are payable upon a contingent event, we have not recorded them our financial statements. At June 30, 2015, cumulative unpaid dividends for the Series A preferred stock totaled $100,822, which shall become payable in shares of common stock immediately prior to the closing of this offering.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with GAAP. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonably based upon information available to us at the time that we make these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. The accounting policies that reflect our more significant estimates and judgments and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results are described below.

The following is not intended to be a comprehensive list of all of our accounting policies or estimates. Our accounting policies are more fully described in Note 2 — *Summary of Significant Accounting Policies*, in our audited financial statements included elsewhere in this prospectus.

Income Taxes

We utilize the liability method of accounting for income taxes as required by Accounting Standards Codification (ASC) 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. Currently, there is no provision for income taxes, as we have incurred operating losses to date, and a full valuation allowance has been provided on the net deferred tax assets. MLT was treated as a partnership for federal and state income tax purposes. Accordingly, no provision was made for income taxes for periods prior to October 30, 2014, since the net losses incurred up to that time (subject to certain limitations) was passed through to the income tax returns of its members. Upon incorporation on October 30, we become taxable as a corporation.

Since incorporation, we have filed U.S. federal and Michigan state income tax returns. Our deferred tax assets were primarily comprised of federal and state tax net operating loss carryforwards, acquired intangibles and tax credit carryforwards and were recorded using enacted tax rates expected to be in effect in the years in which these temporary differences are expected to be utilized. As of December 31, 2014, the tax effect of our federal and state net operating loss carryforwards was approximately $83,000 and $10,000, respectively, and our federal research and development credit carryforward was $114. As of June 30, 2015, the tax effect of our federal and state net operating loss carryforwards was approximately $0.8 million and $0.1 million, respectively, and our federal research and development credit carryforward was $29,000. We did not have any state research and development credit carryforwards. The federal net operating loss and tax credit carryforwards will expire in 2034 if not utilized. The state net operating loss carryforwards will expire in 2024 if not utilized.

Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of certain net

operating loss and tax credit carryforwards before their utilization. However, due to uncertainties surrounding our ability to generate future taxable income to realize these tax assets, a full valuation allowance has been established to offset our deferred tax assets.

Convertible Preferred Stock

We initially record preferred stock that may be redeemed at the option of the holder, or based on the occurrence of events outside our control, in mezzanine equity at the value of the proceeds received. Subsequently, if it is probable that the preferred stock will become redeemable, we recognize changes in the redemption value immediately as they occur and adjust the carrying amount of the instrument to equal the redemption value at the end of each reporting period. If it is not probable that the preferred stock will become redeemable, we do not adjust the carrying value. In the absence of retained earnings these charges are recorded against additional paid-in-capital, if any, and then to accumulated deficit.

Share-Based Compensation

Our share-based compensation for share-based awards is accounted for in accordance with authoritative guidance and is estimated at the grant date based on the fair value of the award and recognized as expense ratably over the requisite vesting period of the award, net of estimated forfeitures. Determining the appropriate fair value of share-based awards requires judgment. We calculate the fair value of each award to employees on the date of grant based on the fair value of our common stock. See "— Common Stock Valuation" below.

We calculate the fair value of each stock option award to employees on the date of grant under the Black-Scholes option-pricing model using certain assumptions related to the fair value of our common stock, the option's expected term, our expected stock price volatility, risk free interest rates and our expected dividend rate.

For options to purchase common stock issued to non-employees, including consultants, we record share-based compensation based on the fair value of the options. We calculate the fair value of each share-based award to non-employees on each measurement date based on the fair value of our common stock. The fair value of options granted to non-employees is remeasured as the options vest and is recognized in the statements of operations during the period the related services are rendered.

The fair value of each stock option grant was determined using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

- *Fair Value of Common Stock.* As discussed below in "— Common Stock Valuation," because there is no public market for our common stock as we are a private company, our board of directors has determined the fair value of the common stock by considering a number of objective and subjective factors, including based on contemporaneous valuations of our common stock performed by an unrelated valuation specialist. The fair value of our common stock will be determined by our board of directors until such time as our common stock is listed on an established stock exchange.

- *Expected Term.* The expected term represents the period that share-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the share-based awards. The expected term for options issued to nonemployees is the contractual term.

- *Expected Volatility.* Since we do not have a trading history of our common stock, the expected volatility was derived from the historical stock volatilities of comparable peer public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the share-based awards.

- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the share-based awards' expected term.

- *Expected Dividend Rate.* The expected dividend is zero as we have not paid and do not anticipate paying any dividends on our common stock for the foreseeable future.

- *Forfeiture Rate.* The forfeiture rate is estimated based on an analysis of actual forfeitures. Management will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from management's estimates, we might be required to record adjustments to share-based compensation in future periods.

The estimated grant-date fair value of our share-based awards was calculated using Black-Scholes option-pricing model, based on the following assumptions for the following periods presented:

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
			(unaudited)	
Expected term (in years)	—	—	—	5.23
Expected volatility	—	—	—	68.07%
Risk-free interest rate	—	—	—	1.63%
Expected dividend rate	—	—	—	0%

If any of the assumptions used in the Black-Scholes option-pricing model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

For 2013 and 2014, share-based compensation was $0 and $54,000, respectively. For the six months ended June 30, 2014 and 2015, share-based compensation expense was $0 and $87,000, respectively. As of June 30, 2015, we had unrecognized share-based compensation totaling $159,000, of which $56,000 will vest upon the satisfaction of a performance condition that will be achieved upon the closing of this offering.

Based upon assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, the aggregate intrinsic value of options outstanding as of June 30, 2015 was approximately $ million, of which approximately $ million related to vested options and approximately $ million related to unvested options.

Common Stock Valuation

In the absence of a public trading market for our common stock, on each grant date, we develop an estimate of the fair value of our common stock in order to determine an exercise price for each share-based award. We have determined the fair value of our common stock using methodologies, approaches and assumptions consistent with the *American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including having contemporaneous and retrospective valuations of our common stock performed by an unrelated valuation specialist, valuations of comparable securities transactions, sales of our convertible preferred stock to unrelated third parties, the rights preferences and privileges of our common stock versus our preferred stock, our operating and financial

performance, our stage of development, current business conditions, our projections, business developments, the lack of liquidity of our capital stock and general and the industry specific economic outlook.

For our common stock valuations performed from November 1, 2014 up until the issuance of our Series A convertible preferred stock (the Series A preferred stock) in March 2015, the fair value of our common stock was estimated entirely using a hybrid of two market approaches, specifically a proposed Series A preferred stock *Securities Transaction — Backsolve* method and the Series A preferred stock post-money value. This later approach considers the implied equity value based on a common equivalent capitalization table associated with an IPO exit. Once the Series A preferred stock round was consummated in March 2015, common stock valuations began to rely on the indications of value realized in the transaction. The fair value of our common stock was estimated using a hybrid of two market approaches, specifically the realized Series A preferred stock *Recent Securities Transaction — Backsolve* method and the Series A preferred stock post-money value. This later approach considers our implied equity value based on a common equivalent capitalization table associated with an IPO exit.

We considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. The methods we used consisted of the following:

- *Option pricing method (OPM).* Under the option pricing method, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options.

- *Probability-weighted expected return method (PWERM).* The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Our per share common stock value was estimated by allocating the equity value using a hybrid combination of OPM and PWERM. We used either PWERM or a combination of the OPM and the PWERM as described above to allocate the equity value to each element of our capital structure, including our common stock. For both approaches, we applied a discount to the valuations due to the lack of marketability of the ordinary shares. We calculated the discount for lack of marketability using a Finnerty model and applied it as appropriate to each allocation.

The dates of our valuations did not always coincide with the dates of our option grants. In such instances, management's estimates were based on the most recent valuation of shares of our common stock. For grants occurring between valuation dates, for financial reporting purposes, we considered the preceding valuations and our assessment of additional objective and subjective factors we believed were relevant as of the grant date to determine the fair value of our common stock.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have any off-balance sheet financing arrangements. In addition, we did not have during the periods presented, and we do not currently have any interest in entities referred to as variable interest entities, which includes special purpose entities and other structured finance entities.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-11, *Income Taxes — Topic 740*, which is an amendment to the accounting guidance on income taxes. This guidance provides clarification on the financial statement presentation of an

unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The amendment was effective for us for interim and annual periods beginning after December 15, 2013, with early adoption permitted. The adoption of this standard did not have a material impact on our financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers — Topic 606*, which supersedes the revenue recognition requirements in FASB ASC 605. The new guidance primarily states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In 2015 the FASB agreed to allow companies to delay the implementation of this standard for one year effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is permitted only for periods beginning after December 15, 2016. We are evaluating its implementation method and the impact of adopting this prospective guidance on our financial statements.

In June 2014, the FASB issued ASU 2014-10, *Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. This guidance removed all incremental financial reporting requirements from GAAP for development stage entities, thereby improving financial reporting by eliminating the cost and complexity associated with providing that information. The effective date of the amendment is staggered for public and nonpublic entities with the first date being for annual periods beginning after December 15, 2014, with early adoption permitted for financial statements that have not yet been issued or available to be issued. We elected to adopt this standard early to take effect in the financial statements and related notes appearing elsewhere in this prospectus.

In June 2014, the FASB issued ASU 2014-12, *Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* (ASU 2014-12). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in ASC 718, as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (1) prospectively to all awards granted or modified after the effective date; or (2) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard is not expected to have a material impact on our financial statements.

In August 2014, the FASB issued Accounting Standards Update 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), which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable) and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. We elected to adopt this standard early to take effect in the financial statements and related notes appearing elsewhere in this prospectus.

In January 2015, the FASB issued ASU 2015-01, *Income Statement — Extraordinary and Unusual Items* (ASU 2015-01). ASU 2015-01 eliminates from GAAP the concept of extraordinary items. As a result, an entity will no longer be required to separately present an extraordinary item on its statement of

comprehensive loss, net of tax, after income from continuing operations, or disclose income taxes and net income per share data applicable to an extraordinary item. However, ASU 2015-01 will still retain the presentation and disclosure guidance for items that are unusual in nature and occur infrequently. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted provided the guidance is applied from the beginning of the fiscal year of adoption. We do not expect the adoption of this standard to have a material impact on our financial statements, absent any material transactions in future periods that would qualify for extraordinary item presentation under the prior guidance.

In April 2015, the FASB issued ASU 2015-03, *Interest — Imputation of Interest* (ASU 2015-03). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. For public entities, ASU 2015-03 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. We do not expect the adoption of this standard to have a material impact on our financial statements.

Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position is the potential loss arising from adverse changes in interest rates. As of December 31, 2014, we had cash and cash equivalents of $0.3 million. We generally hold our excess cash in interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 permits emerging growth companies such as us to delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease. Dyslipidemia is generally characterized by an elevation of low-density lipoprotein cholesterol (LDL-C), or bad cholesterol, triglycerides, or fat in the blood, or both. We are developing our product candidate gemcabene (CI-1027), a novel, once-daily, oral therapy, for patients who are unable to achieve normal levels of LDL-C or triglycerides with currently approved therapies, primarily statin therapy. Gemcabene's dual mechanism of action is designed to both inhibit the production of fatty acids and cholesterol in the liver and enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in 895 subjects, which we define as healthy volunteers and patients, across 18 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

Cardiovascular disease is a major health concern, causing more deaths globally than any other disease. Dyslipidemia is generally viewed as an important predictor of cardiovascular events including heart attack and stroke, and a cause of cardiovascular disease. It comprises one of the largest therapeutic areas with annual worldwide drug sales of approximately $22 billion in 2013. We estimate more than 40% of Americans have LDL-C or triglycerides, or both, above a normal range. Statins, such as Lipitor, marketed by Pfizer Inc. (Pfizer), and Crestor, marketed by AstraZeneca Pharmaceuticals LP (AstraZeneca), among others, are standard of care for LDL-C lowering, while fibrates, prescription fish oils and niacin are standard of care for triglyceride lowering. Although these drugs are highly prescribed and capable of reducing LDL-C and triglyceride levels, many patients are unable to effectively manage their dyslipidemia with currently approved therapies and are in need of better treatment alternatives. For example, approximately 40% of patients on statins are unable to meet their LDL-C lowering goal, and doubling a statin dose has shown to incrementally lower LDL-C levels by a nominal percentage (approximately 6% based on historical evidence), while increasing safety and tolerability concerns. An even higher percentage of patients with severe hypertriglyceridemia do not achieve triglyceride levels low enough to reduce the risk of developing co-morbidities such as pancreatitis.

We believe gemcabene possesses a differentiated product profile compared to other therapies in the market and in clinical development. Key attributes of our product candidate include the following:

- **Cost-effective, once-daily, oral therapy.** Gemcabene is a small molecule formulated as a tablet and is cost effective to manufacture. As a once-daily, oral therapy, gemcabene, if approved, would be more convenient than other non-statin therapies, many of which require frequent injections or multiple daily doses.

- **Promising safety and tolerability.** Gemcabene was observed to be well tolerated in 895 subjects across 18 Phase 1 and Phase 2 trials both as monotherapy and in combination with statins. No subjects died and no subjects experienced a serious adverse event (SAE) that was considered to be related to gemcabene. Adverse events (AEs) reported were generally mild to moderate in intensity. Gemcabene did not appear to increase the reporting of myalgia (muscle pain) when added to statin therapy and no treatment related events of myalgia were reported in any gemcabene monotherapy arm in the dyslipidemia trials.

- **Significant lipid-lowering of LDL-C, high-sensitivity C-reactive protein (hsCRP) and triglycerides.** In Phase 2 trials, patients with hypercholesterolemia treated with gemcabene as monotherapy were observed to have significantly lowered LDL-C by approximately 30% from baseline and significantly lowered hsCRP by approximately 40% from baseline. In addition, patients with hypertriglyceridemia (³200 mg/dL) were observed to have significantly lowered triglycerides by approximately 40%, and based on post-hoc analysis, gemcabene was observed to lower triglycerides by up to 60% in patients with severe triglyceride levels (³500 mg/dL). Our product candidate's ability to meaningfully lower

levels of multiple key lipids attributable to cardiovascular disease may expand its use across multiple indications within the dyslipidemia market.

- **Additive effect in combination with statins.** In a Phase 2 trial in patients with uncontrolled hypercholesterolemia while on stable statin therapy, gemcabene was observed to significantly lower LDL-C by an additional 25% to 31% from baseline. This data indicates that gemcabene may better treat a large population of patients who are unable to reach their lipid goal with statins and other currently prescribed therapies.

- **No drug-drug interactions when combined with high-intensity statin doses.** In two Phase 1 trials, gemcabene was tested in combination with high-intensity statin doses, 80 mg simvastatin and 80 mg atorvastatin. No clinically relevant drug-drug interactions were observed. In addition, gemcabene has been formulated as a fixed-dose combination tablet with various atorvastatin doses, which may offer additional convenience and compliance to patients.

We are initially pursuing gemcabene in the following four indications as a treatment in addition to maximally tolerated statin therapy for patients who are unable to reach their lipid-lowering goals:

- homozygous familial hypercholesterolemia (HoFH), a rare genetic lipid disorder which results in elevated LDL-C usually due to mutations in both alleles, a pair of genes on a chromosome responsible for a specific trait, of the LDL-receptor gene;

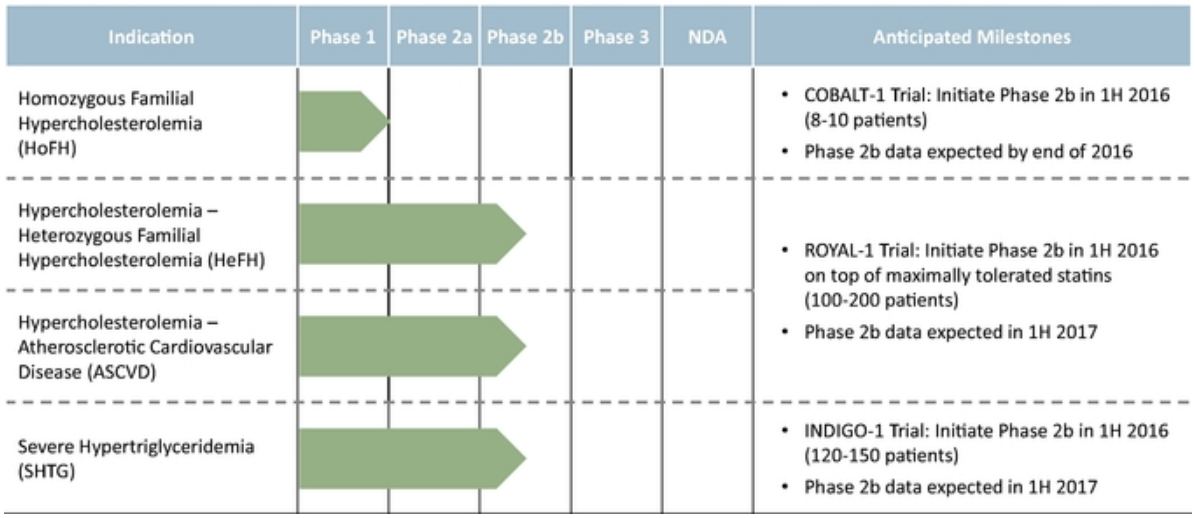
- heterozygous familial hypercholesterolemia (HeFH), a more prevalent genetic lipid condition which results in elevated LDL-C usually due to a mutation in one allele of the LDL-receptor gene;

- atherosclerotic cardiovascular disease (ASCVD), patients with hypercholesterolemia, or patients with elevated LDL-C who have had or are at risk for a cardiovascular event, such as heart attack or stroke; and

- severe hypertriglyceridemia (SHTG), in which patients with elevated triglycerides are at an increased risk of developing co-morbidities such as pancreatitis.

We are pursuing HoFH given that gemcabene has recently received orphan drug designation for this indication. We believe we can design an efficient development plan to provide a new treatment alternative for those patients. Furthermore, we believe that gemcabene's potential ability to treat patients in the most severe segment of the dyslipidemia market, HoFH, will enhance brand awareness among key thought leaders and physicians. We are developing gemcabene for HeFH, ASCVD and SHTG given gemcabene's: (1) promising clinical data in these indications; (2) cost-effective manufacturing process; (3) convenient oral dosing; (4) viability as adjunct combination therapy; and (5) large commercial potential. In the first half of 2016, we expect to initiate three Phase 2b trials for gemcabene in HoFH, hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins, and SHTG.

Gemcabene Pipeline Indications



Upon completion of our Phase 2b trials, we intend to request an End of Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) to reach an agreement on the design of Phase 3 registration trials and long-term safety exposure for our target indications. We intend to pursue similar discussions with Canadian and European health authorities. We believe it is unlikely the FDA will require us to initiate cardiovascular outcome trials for our target indications. The FDA has not required the initiation or completion of cardiovascular outcome trials for recent approvals of dyslipidemia therapies, including non-statin therapies targeting LDL-C lowering for the treatment of HoFH, HeFH and ASCVD and triglyceride lowering for treatment of SHTG. Cardiovascular outcome trials require evaluation of cardiovascular clinical conditions in large patient populations over a long period of time and are both costly and time-consuming. However, for commercial and competitive reasons, such as the potential to broaden the label claims, we intend to review with the FDA a design for a cardiovascular outcome trial which we may initiate shortly before an NDA submission and complete post-approval.

Our company was co-founded by former Pfizer employees, Dr. Charles Bisgaier and David Lowenschuss, who were responsible for licensing exclusive worldwide rights to gemcabene from Pfizer in April 2011. Prior to co-founding the original Esperion Therapeutics, Inc. (Esperion) in 1998, which was acquired by Pfizer in 2004, Dr. Bisgaier worked at Parke-Davis, a division of Warner-Lambert Company from 1990 to 1998, and was instrumental in the discovery and development of gemcabene, as well as the development of Lipitor and Lopid. Many of our employees and consultants have been involved in the historical development of gemcabene and other innovative dyslipidemia product candidates in development, including ETC-216, a synthetic HDL based on ApoAI-Milano (developed by the original Esperion, Pfizer and currently The Medicines Company), ACP-501 (developed by AlphaCore Pharma, later acquired by AstraZeneca) and ETC-1002 (developed by the original Esperion, Pfizer and the current Esperion). We have organized a medical advisory board with key opinion leaders including Drs. John Kastelein, Evan Stein, Robert Hegele and Dirk Blom who are recognized worldwide experts in the drug development of lipid-lowering therapies. The management team, led by our CEO Mina Sooch, has significant experience in operating and financing biopharmaceutical companies with a successful track record of discovering, developing and commercializing treatments in the cardiovascular and orphan markets.

Our Strategy

Our goal is to become a leading cardio-metabolic biopharmaceutical company that develops and commercializes best-in-class therapies for patients and provides attractive solutions for physicians and payors.

The core elements of our strategy to achieve our goal are the following:

- ***Advance the late-stage clinical development of gemcabene across multiple target indications.*** We are focused on a broad spectrum of indications for dyslipidemia patients ranging from the orphan indication HoFH to more prevalent conditions, such as HeFH, ASCVD and SHTG. The data from our 18 Phase 1 and Phase 2 trials and multiple preclinical studies have provided us with a comprehensive set of information and key insights into gemcabene's mechanism of action, lipid-lowering effects and safety profile. Furthermore, recent approvals of cardiovascular therapies in gemcabene's target indications, such as biologic PCSK9 inhibitors for HoFH, HeFH and ASCVD and prescription fish oils for SHTG have provided us with a better understanding of current FDA views on approval of new dyslipidemia drugs. As a result, we believe that we have identified indications for gemcabene with favorable regulatory pathways and the highest likelihood of commercial success. During the first half of 2016, we plan to initiate three Phase 2b trials for gemcabene: an 8 to 10 patient trial for HoFH, a 100 to 200 patient trial for hypercholesterolemia on maximally tolerated statins, including HeFH and ASCVD patients, and a 120 to 150 patient trial for SHTG. We expect top-line results from these trials starting at the end of 2016 continuing through 2017.

- ***Pursue oral combination opportunities for gemcabene.*** Oral combination therapy is the current paradigm for the treatment of dyslipidemia, as patients typically require multiple drugs to address their dyslipidemia as well as other co-morbidities. Based on existing data demonstrating additive effects on LDL-C and triglyceride lowering as well as no drug-drug interactions with statins, we believe that gemcabene has the potential to be developed as a fixed-dose combination with low to high dose statins, which, if approved, may enhance adoption in the market and patient compliance. As part of our development strategy, we plan to formulate and manufacture gemcabene in fixed-dose combination with statins and/or other lipid-lowering agents.

- ***Continue to build out our patent portfolio for gemcabene.*** We believe our patents and patent applications provide us with a significant competitive advantage. We have 24 issued patents and 18 pending patent applications for gemcabene in the United States and internationally directed to formulations, compositions, methods of use and methods of manufacturing. We intend to aggressively prosecute and defend our patent portfolio and pursue new patents in order to ensure the long term commercial success of gemcabene.

- ***Maximize the global commercial value of gemcabene.*** We have retained all commercial and manufacturing rights to gemcabene. We intend to evaluate our strategic alternatives to collaborate with global biopharmaceutical companies for the development and commercialization of gemcabene. We believe we could independently commercialize gemcabene for the treatment of patients with HoFH in the United States with a targeted sales force and would seek commercial partners outside of the United States. For larger indications, such as HeFH, ASCVD and SHTG, we would assess partnership opportunities for Phase 3 development and the worldwide commercialization of gemcabene.

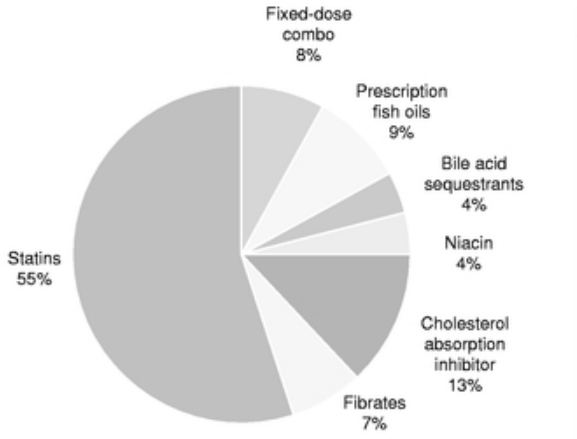
- ***Leverage the expertise and experience of our management team to evaluate future in-licensing and acquisition opportunities.*** Across our leadership team, we have discovered and/or developed Lipitor, Lopid, ETC-1002, ETC-216, ACP-501, Vaprisol and PNT-2258, and commercialized many lipid regulating and orphan drugs including Crestor, Myalept and Lynparza. Our team is well-qualified to identify and in-license or acquire clinical-stage cardio-metabolic assets, and we intend to evaluate these opportunities to diversify our pipeline and generate long-term growth.

Overview of Dyslipidemia Market

According to the World Health Organization, cardiovascular disease is the number one cause of death in the world, responsible for 17.5 million, or approximately one in three, deaths in 2012. Cardiovascular disease is influenced by both environment and genetics. Environmental factors include diet, smoking, excess weight and sedentary lifestyle. Genetic defects can cause certain types of cardiovascular disease, such as familial hypercholesterolemia, a condition in which mutations on a gene are responsible for the elevated LDL-C levels in patients.

Dyslipidemia is characterized by an elevation of LDL-C, triglycerides or both. Dyslipidemia is viewed as an important predictor of cardiovascular events, including heart attack and stroke, and a cause of cardiovascular disease. It is estimated that 71 million American adults, or approximately 33%, have high LDL-C levels, which is a major risk factor for cardiovascular disease. Furthermore, it is estimated that over 30% of American adults have elevated triglycerides above 150 mg/dL, and high levels of triglycerides are even evident in patients with normal cholesterol levels. If untreated, high levels of triglycerides may lead to more serious illnesses, such as atherosclerosis (plaque build-up in the arteries) and pancreatitis (inflammation of the pancreas). The dyslipidemia market has achieved approximately $22 billion in worldwide drug sales in 2013 and remains one of the largest therapeutic markets.

Global Dyslipidemia Market
2013 Worldwide Drug Sales of $22 Billion



Source: Dyslipidemia Metabolic Disorders Study from Decision Resources (2015).

Indication	Approved Therapies
HoFH	▪ Statins ▪ Cholesterol absorption inhibitor (ezetimibe) ▪ Juxtapid ▪ Kynamro ▪ PCSK9 inhibitors*
Hypercholesterolemia (HeFH, ASCVD)	▪ Statins ▪ Ezetimibe ▪ Fixed-dose combo (statins + ezetimibe) ▪ Bile acid sequestrants ▪ PCSK9 inhibitors*
SHTG	▪ Fibrates ▪ Prescription fish oils ▪ Niacin ▪ Statins

* Recently approved

Recent Developments in the Dyslipidemia Market

In 2015 there have been key advisory panel meetings and regulatory approvals for non-statin LDL-C lowering drugs. Specifically, New Drug Applications (NDAs) for two PCSK9 inhibitors have been considered by the FDA and have subsequently been approved in the United States. We believe these approvals signal the FDA's continued view that change in LDL-C levels is an acceptable surrogate endpoint for a drug approval in certain lipid indications and that cardiovascular outcome trials would not required for such approvals. All approved product labels indicate cardiovascular morbidity and mortality have not yet been determined. Some of the key regulatory events in the dyslipidemia market are highlighted below.

- On August 27, 2015, Repatha, developed by Amgen Inc. (Amgen), was approved in the United States for use along with diet and maximally tolerated statin therapy in adults with HoFH, HeFH and ASCVD, who need additional lowering of LDL-C.

- On July 24, 2015, Praluent, developed by Regeneron Pharmaceuticals, Inc. (Regeneron) and Sanofi-Aventis U.S., LLC (Sanofi), was approved in the United States for use as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH and ASCVD, who require additional lowering of LDL-C.

- On July 21, 2015, the European Commission approved Repatha, developed by Amgen, with a broader label compared to that in the United States. The approved indications in Europe included the treatment of adults with primary hypercholesterolemia or mixed dyslipidemia as: (1) combination therapy with maximally tolerated dose of statin or statin and other lipid-lowering drugs; or

(2) monotherapy or combination therapy with other lipid-lowering drugs in patients who are statin-intolerant, or for whom statin is contraindicated. Repatha is also approved for the treatment of HoFH in adults and adolescents aged 12 years and over in combination with other lipid-lowering drugs.

In November 2014, at the American Heart Association meeting, Merck & Co., Inc. (Merck) announced data for ezetimibe from its IMPROVE-IT cardiovascular outcome trial which was conducted over seven years. The data showed that the addition of ezetimibe to 40 mg simvastatin achieved the trial's primary endpoint, reduction in composite outcome events, comprised of cardiovascular death, myocardial infarction (MI), unstable angina requiring hospitalization, coronary revascularization and stroke, by 6.4% more than patients who received simvastatin alone (p=0.016). We believe this reconfirmed the LDL-C lowering hypothesis for the cardiovascular field which has been supported by historical data showing a linear relationship between LDL-C and mortality from coronary heart disease.

In August 2015, current Esperion announced guidance from its EOP2 meeting with the FDA for its LDL-C lowering product candidate, ETC-1002. The press release indicated the FDA's confirmation to Esperion that LDL-C remains an acceptable clinical surrogate endpoint for the approval of an LDL-C lowering therapy, such as ETC-1002 in patient populations who have a high unmet medical need, including patients with HeFH and ASCVD, who are already taking maximally tolerated statins yet require additional LDL-C reduction and where there is a positive benefit/risk ratio.

Collectively, recent approvals of new cardiovascular drugs, results from clinical trials of non-statin product candidates, and regulatory guidance have provided us with some assurance that LDL-C lowering product candidates in development will not be required to conduct cardiovascular outcome trials in the United States or Europe prior to approval for our target indications. In 2015, we also held an initial meeting with the FDA in which we received guidance on our HoFH program.

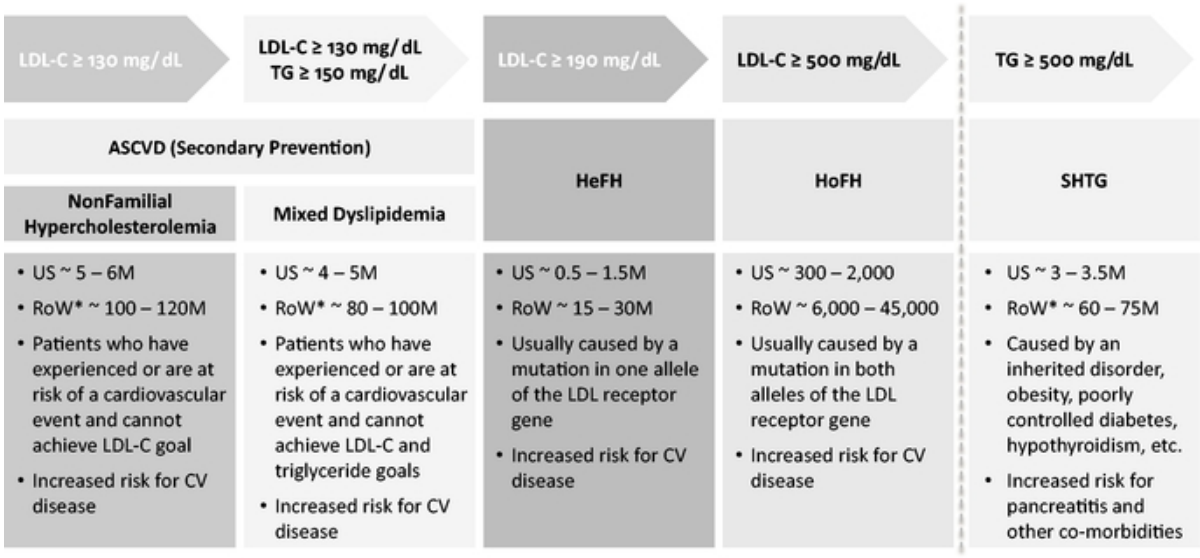
hsCRP Biomarker of Interest

Inflammation plays a significant role in the propagation of atherosclerosis and susceptibility to cardiovascular events. Of the wide array of inflammatory biomarkers that have been studied, hsCRP has received the most attention for its use in risk reclassification of cardiovascular disease. Recently, at the 2015 European Society for Cardiology meeting, Merck presented a post-hoc analysis of the IMPROVE-IT trial which confirmed the importance of lowering both LDL-C and hsCRP levels to below 70 mg/dL and 2 mg/L, respectively, with a 27% relative risk reduction in cardiovascular events occurring in patients that were able to attain target levels. These findings support the potential for novel non-statin therapies that can demonstrate clinical efficacy in both LDL-C and hsCRP reduction. Gemcabene's ability to substantially lower hsCRP in conjunction with LDL-C may offer further benefit to the cardiovascular health of patients.

Our Target Indications

We are developing gemcabene as a treatment for dyslipidemia patients for whom existing treatments are insufficient. Despite approval of new drugs, including injectable PCSK9 inhibitors, we believe physicians, patients and payors continue to seek efficacious add-on therapies. We believe that oral, once-daily gemcabene, if approved, presents a significant opportunity across multiple indications. These indications span from HoFH to more prevalent conditions, such as HeFH, ASCVD and SHTG, in which therapies are required to reduce elevated levels of LDL-C, triglycerides or both. Our target indications are summarized in the diagram below with a total of approximately 14 million addressable patients in the United States who could be treated with gemcabene, with an even larger number in the rest of world.

Dyslipidemia Market Landscape and Total Addressable Patients



Source: Company estimates.

(*) Addressable market for rest of the world is estimated by extrapolating from the U.S. addressable market.

Definitions: M=millions, CV=cardiovascular, TG=triglycerides.

Homozygous Familial Hypercholesterolemia (HoFH)

HoFH is a rare genetic disease that is usually caused by a mutation in both alleles of the LDL receptor gene responsible for removing LDL from the blood. As a result, HoFH patients exhibit severely high LDL-C levels, are at very high risk of experiencing premature cardiovascular events, such as a heart attack or stroke, and develop premature and progressive atherosclerosis. LDL-C levels in HoFH patients are typically in the range of 500 mg/dL to 1,000 mg/dL, compared to a normal target range of 70 mg/dL to 100 mg/dL. Unless treated, most patients with HoFH do not survive adulthood beyond 30 years of age. There are approximately 300 to 2,000 HoFH patients in the United States and 6,000 to 45,000 patients in the rest of the world based on an estimated prevalence rate of one in 160,000 to one in one million.

Current available treatments for HoFH generally include a combination of dietary intervention, statins, ezetimibe and other approved LDL-C lowering therapies, including lipoprotein apheresis. However, even when combination therapies are utilized, many patients still have high LDL-C levels and are still at high risk of cardiovascular disease. The FDA has approved two non-statin therapies for HoFH, Juxtapid, marketed by Aegerion Pharmaceuticals, Inc. (Aegerion), and Kynamro, marketed by Sanofi. Although these drugs have demonstrated efficacy, they have significant safety and tolerability issues, including boxed warnings for liver toxicity on the product labels. Recently, the FDA has also approved Amgen's PCSK9 inhibitor, Repatha, for HoFH patients, but this therapy has limitations due to its mechanism of action reliant on functional LDL-receptors. In clinical trials, Repatha has shown substantially less LDL-C lowering from baseline in patients with HoFH compared to LDL-C lowering in patients with other hypercholesterolemia indications.

On February 6, 2014, gemcabene received orphan drug designation by the FDA for treatment of HoFH. We believe that pursuing the HoFH indication may enable gemcabene to reach the market sooner than for other indications due to: (1) approval pathway based on a single, small Phase 3 trial; (2) no requirement for cardiovascular outcome trials; and (3) potential for priority review by the FDA in light of the unmet medical need in this orphan population. Furthermore, we believe that gemcabene's potential to treat patients in the

most severe segment of the dyslipidemia market will enhance brand awareness among key thought leaders and physicians.

Heterozygous Familial Hypercholesterolemia (HeFH)

The HeFH patient population is generally comprised of individuals who have one defective gene that leads to elevated LDL-C levels between 190 mg/dL and 500 mg/dL. These patients are prone to cardiovascular events. The incidence of patients with HeFH is estimated to be between one in 200 and one in 500, and accordingly, we estimate there are approximately 0.5 to 1.5 million patients with HeFH in the United States and 15 to 30 million in the rest of the world.

Current available treatments for HeFH include statins, ezetimibe, bile acid sequestrants and the recently approved injectable PCSK9 inhibitors. Despite the availability of various treatments, many patients are still unable to achieve recommended LDL-C levels. In addition, patients, physicians and payors may prefer more convenient, cost-effective, oral drugs.

We believe obtaining approval for the HeFH indication will enable gemcabene to reach a large market of patients with the inability to attain their LDL-C goal using current therapies. An approval in HeFH would allow gemcabene to be introduced into another indication for very high LDL-C levels and enable physicians globally to have another oral option in treating this complex patient population.

Atherosclerotic Cardiovascular Disease (ASCVD)

ASCVD represents patients who have experienced or are at risk of a cardiovascular event and are unable to meet their LDL-C lowering goal of less than 70 mg/dL with maximally tolerated statin therapy. This population also includes many patients who, in addition to not being able to meet their LDL-C lowering goal, have elevated triglyceride levels greater than 150 mg/dL and less than 500 mg/dL, categorized as mixed dyslipidemia. If both cholesterol and triglyceride levels are high, it is difficult for physicians to optimize the right combination of current therapies to reach lipid level goals, as for many patients, lowering the level of one may increase the level of the other. We estimate that approximately 10 million patients in the United States and 200 million patients in the rest of the world have a need for additional therapies to effectively and safely bring them closer to their LDL-C and triglyceride lowering goals.

Current available treatments for both primary hypercholesterolemia and ASCVD include statins, ezetimibe, bile acid sequestrants, niacin, fibrates and recently approved PCSK9 inhibitors. While these drugs have demonstrated efficacy in lipid-lowering in this population, some of these do not sufficiently address the patients with mixed dyslipidemia who need to lower both LDL-C and triglycerides.

We believe that there is a meaningful number of underserved ASCVD patients who are: (1) unable to reach LDL-C and triglyceride goals on maximally tolerated statin therapy; (2) require LDL-C reduction beyond the 6% reduction observed when statin dose is doubled; or (3) unable to tolerate higher doses of statins. If gemcabene is approved for this indication, it may potentially offer patients a preferred combination therapy with statin that is convenient, cost effective, well tolerated and effective in achieving LDL-C and triglyceride goals.

Severe Hypertriglyceridemia (SHTG)

Elevated triglycerides are often caused by an inherited disorder or exacerbated by uncontrolled diabetes mellitus, obesity, hypothyroidism and sedentary habits. A recent scientific statement on "Triglycerides and Cardiovascular Disease" issued by the American Heart Association based on a review of the pivotal role of triglycerides in lipid metabolism, reaffirmed that triglycerides are not directly atherogenic, but represent an important biomarker of cardiovascular disease. Patients with severe triglycerides greater than 500 mg/dL, or SHTG, have increased risk of developing pancreatitis, a painful and potentially life-threatening inflammation of the pancreas. Based on a 1.1% prevalence rate in the United States, as published by the American Heart Association, we estimate there are approximately 3.5 million patients with SHTG in the United States and 75 million patients in the rest of the world.

Current available treatments for SHTG consist of dietary modifications to lower the intake of fatty foods and the use of fibrates, prescription fish oils and niacin. These treatments are often inadequate in lowering triglyceride levels below 500 mg/dL, the level at which patients are at an increased risk for developing pancreatitis. Due to the severely elevated triglyceride levels in this patient population, reducing triglyceride levels below 500 mg/dL may require reductions in triglyceride levels of 40% or more. Current therapies, even in combination, are often insufficient in achieving such a result. In addition, many of the existing treatments do not combine well with statins for treating SHTG.

We believe that pursuing SHTG may enable gemcabene to reach a large population of patients with triglyceride levels above 500 mg/dL and offer a convenient, oral therapy that may have the potential to result in better efficacy than standard of care, especially in combination with statins.

Our Product Candidate — Gemcabene

Our product candidate, gemcabene, is a novel, once-daily, oral therapy designed to target known lipid metabolic pathways to lower levels of LDL-C, hsCRP and triglycerides. Gemcabene shares many of the attributes of statin therapy, including broad therapeutic applications, convenient route of administration and cost-effective manufacturing process, but does not appear to increase the reporting of myalgia when added to statin therapy. Gemcabene has also shown additive LDL-C lowering in combination with stable low, moderate or high intensity statin therapy. We also plan to develop a fixed-dose combination product of gemcabene with atorvastatin to enhance market adoption and maximize the likelihood of commercial success.

We are developing multiple indications for gemcabene, ranging from HoFH, an orphan indication, to more prevalent conditions, such as HeFH, ASCVD and SHTG. During the first half of 2016, we plan to initiate three Phase 2b trials for gemcabene: an 8 to 10 patient trial for HoFH, a 100 to 200 patient trial for hypercholesterolemia on maximally tolerated statins, including HoFH and ASCVD patients, and a 120 to 150 patient trial for SHTG. We expect top-line results from the first of these trials to start reading out at the end of 2016 through 2017.

We licensed global rights to gemcabene from Pfizer in April 2011. We will continue to leverage the extensive preclinical, clinical, manufacturing and formulation work previously conducted to further advance the development of gemcabene.

Mechanism of Action

Gemcabene has a dual mechanism of action that involves: (1) blocking the overall production of hepatic triglyceride and cholesterol synthesis; and (2) enhancing the clearance of VLDL. Based on prior clinical trials, the combined effect for these mechanisms has been observed to result in a reduction of plasma VLDL-C, LDL-C, triglycerides and hsCRP, as well as elevation of high-density lipoprotein cholesterol (HDL-C).

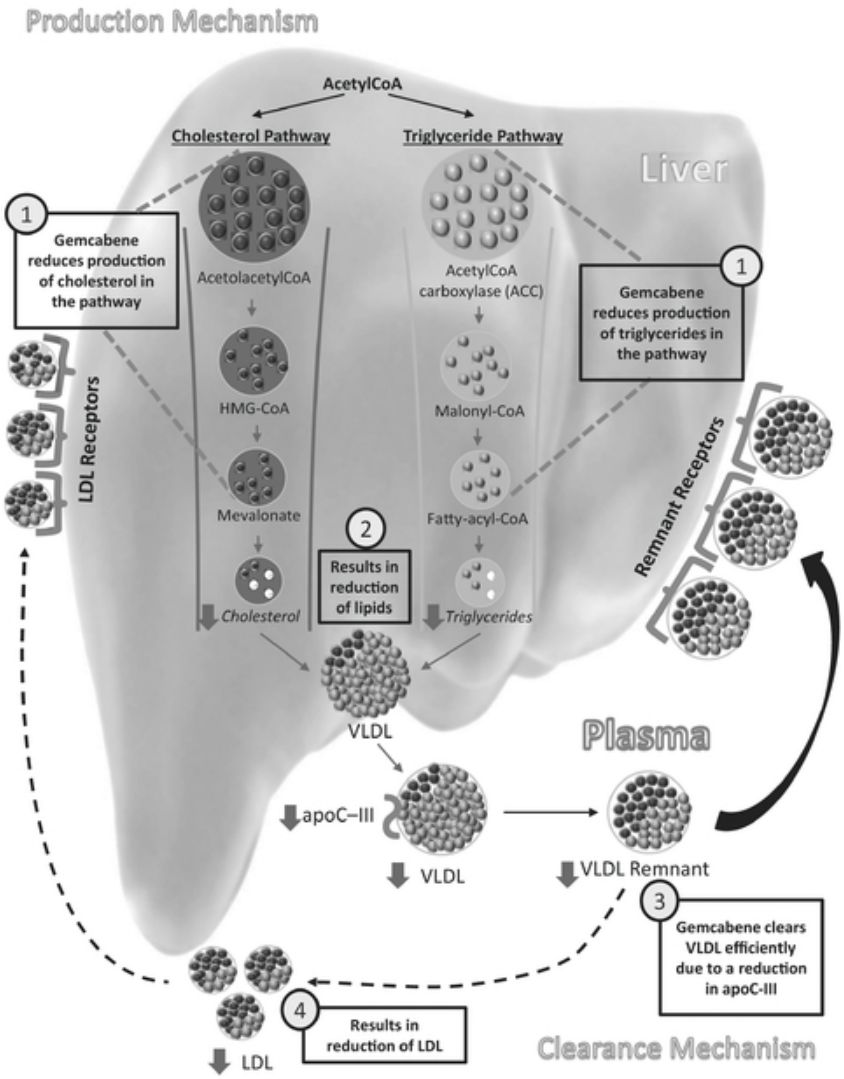
(1) Gemcabene blocks the overall production of hepatic triglycerides and cholesterol. Given its structural similarities to long-chain fatty acid, gemcabene may act as an inhibitor of acetyl CoA carboxylase targeting the rate-limiting enzyme in fatty acid synthesis, subsequently leading to a decreased hepatic triglyceride production. Gemcabene may also inhibit one or more enzymes in the cholesterol synthesis pathway at the step or upstream to where statins interact. In preclinical studies in primary rat hepatocyte and mice models, gemcabene was observed to inhibit both triglyceride and cholesterol production.

(2) Gemcabene enhances the clearance of VLDL by decreasing the production of messenger RNA (mRNA) of the apolipoprotein C-III (apoC-III) gene, thereby decreasing the production of the apoC-III protein. ApoC-III is a small protein that inhibits hepatic uptake of triglyceride-rich particles such as VLDL. VLDL are catabolized to VLDL remnants in plasma. The VLDL remnants are either cleared from the plasma via liver plasma remnant receptors or mature to LDL. The reduction in apoC-III favors the enhanced clearance of the VLDL remnants and reduces the formation of LDL.

We have observed in preclinical studies that gemcabene significantly clears VLDL in the plasma with corresponding reductions in the liver apoC-III mRNA levels and apoC-III plasma protein levels in rats.

The diagram below depicts the novel mechanisms of gemcabene. We will continue to undertake preclinical studies to further clarify gemcabene's involvement in various metabolic pathways.

Gemcabene Novel Mechanism of Action



Clinical Experience

Gemcabene has been assessed in 18 Phase 1 and Phase 2 clinical trials. One Phase 1 trial was not completed when the program was previously discontinued. Across all trials, 1,272 adult subjects, including healthy volunteers and patients with various underlying conditions, such as hypercholesterolemia, hypertriglyceridemia, osteoarthritis and hypertension, participated. Of the subjects, 895 have been exposed to at least one dose of gemcabene.

We believe that gemcabene's efficacy in Phase 1 and Phase 2 trials support our development plan focused on HoFH, HeFH, ASCVD and SHTG patients. Specifically, patients treated with gemcabene were observed to have significantly lowered LDL-C, hsCRP and triglycerides with results from the trials summarized below:

- In a four week, double-blind, multiple dose, Phase 1 trial in 50 healthy subjects (Trial 1027-003), gemcabene monotherapy doses (450 mg, 600 mg and 900 mg) significantly lowered LDL-C from baseline by approximately 30%.

- In an eight week, double-blind, placebo-controlled, Phase 2 trial in 66 patients with elevated LDL-C on background stable statin therapy (Trial 1027-018), both gemcabene doses (300 mg and 900 mg) in combination with statins significantly lowered LDL-C from baseline by approximately 25% to 30%.

- In an eight week, double-blind, placebo-controlled, Phase 2 trial in 277 patients with hypercholesterolemia (Trial A4141001), gemcabene monotherapy doses (300 mg, 600 mg and 900 mg) significantly lowered LDL-C, with the 600 mg and 900 mg doses lowering LDL-C by approximately 30%. Gemcabene monotherapy doses (600 mg and 900 mg) also significantly lowered hsCRP by approximately 40%.

- In a 12-week, double-blind, placebo-controlled, Phase 2 trial (Trial 1027-004), 94 of the 161 patients had elevated triglycerides (³200 mg/dL). For those patients, gemcabene lowered triglycerides in all dose arms, with the 300 mg dose lowering triglycerides by 40%. A post-hoc analysis of nine patients with severe triglyceride levels (³500 mg/dL) treated with 150 mg and 300 mg suggest gemcabene has the potential to lower triglycerides by as much as 60%.

Gemcabene was observed to be well tolerated at single doses up to 1,500 mg and multiple doses up to 900 mg/day. This includes 837 subjects who received multiple doses of up to 900 mg for up to 12 weeks. Safety of the subjects in these trials was evaluated by AE monitoring, clinical laboratory assessments, electrocardiograms (ECGs), physical examinations, and vital sign assessments. Across all trials (1,272 adult subjects), 10 healthy volunteers or patients reported a treatment-emergent SAE, none of which were considered by the clinician to be related to gemcabene. No deaths occurred in any of the trials. AEs reported were generally mild to moderate in intensity with the most common events being headache, weakness, nausea, dizziness, upset stomach, infection and abnormal bowel movements. Gemcabene did not appear to increase the reporting of mylagia when added to statin therapy and no treatment related events of mylagia were reported in any gemcabene monotherapy arm in the dyslipidemia trials. Small mean increases in serum creatinine and blood urea nitrogen (BUN) have been observed in some trials. The increase was reversible with all creatinine values returning to baseline within approximately two weeks of cessation of gemcabene. Elevated levels of liver enzymes, specifically alanine transaminase (ALT) and/or aspartate aminotransferase (AST), were observed in a few patients returning to baseline after cessation of treatment. No clinically meaningful changes were observed in physical examinations or vital signs, including blood pressure.

In addition, gemcabene demonstrated promising clinical pharmacology attributes across 10 completed Phase 1 trials in healthy subjects, such as once-daily dosing, no meaningful drug-drug interactions with high intensity statins and no observed food effect. Gemcabene was observed to: (1) be rapidly absorbed following oral administration with time of maximum concentration within two hours and (2) reach maximum plasma concentration (Cmax) and area under the curve over 24 hours (AUC 0-24) that were dose proportional following both single- and multiple-dose administration. Steady state concentrations were achieved within six days of repeated dose administration. Average half-life ranged from 32 to 41 hours.

Gemcabene's primary route of elimination was renal. In addition, no significant drug-drug interactions were observed with digoxin, a cardiovascular drug for the treatment of atrial fibrillation. There were no observed clinically relevant effects on QTc, a measure of cardiac rhythm, and no observed clinically relevant effect on blood pressure. Renal clearance was slightly decreased and was associated with a slight increase in serum creatinine. Treatment with gemcabene was associated with a mean increase in the percent change from baseline in the glucose disposal rate, but the comparison to placebo was not statistically significant. Based on PK AUC(0-∞) data, the extent of absorption following administration of gemcabene with food was similar to that observed in fasting subjects. Gemcabene can be taken with or without food.

Based on the results of these trials, we believe gemcabene has the potential to have a differentiated profile as an oral once-daily, well tolerated adjunct therapy with promising evidence of efficacy in lowering of LDL-C, hsCRP and triglycerides in patients with dyslipidemia.

Gemcabene Phase 2 Clinical Trials

Gemcabene has been evaluated in seven Phase 2 trials across a diverse patient population. These trials explored safety, tolerability and efficacy and multiple doses of gemcabene as monotherapy and in combination with low, moderate and high intensity statins. The table below summarizes our completed Phase 2 clinical trials.

Summary of Phase 2 Clinical Trials with Gemcabene in Patients

Trial Number	Patient / Indication	Trial Objectives	Doses	# Patients	Duration	Key Lipid and Other Endpoints
1027-004	Hypertriglyceridemia, including SHTG	Double-blind, placebo-controlled, randomized trial to determine the efficacy and safety of gemcabene in subjects with low HDL-C and either normal or elevated triglycerides	150, 300, 600, 900 mg	GEM=129 placebo=32	12 weeks	HDL-C, TG, LDL-C, hsCRP, apoB, Total cholesterol
1027-012	Hypertension	Double-blind, placebo-controlled, randomized trial to determine the effect of gemcabene compared to quinapril	900 mg (with quinapril 20 mg)	GEM=43 quinapril=18 placebo=41	12 weeks	Systolic BP, Diastolic BP
1027-014	Healthy Obese Non-diabetic	Double-blind, placebo-controlled, randomized trial to determine the effect of gemcabene on insulin sensitivity	900 mg	GEM=26 placebo=27	4 weeks	Insulin sensitivity
1027-015	Hypertension	Double-blind, placebo-controlled, randomized trial to determine the effect of gemcabene on blood pressure	900 mg	GEM=23	4 weeks	Systolic BP, Diastolic BP
1027-018	Hypercholesterolemia (not at goal on stable statin)	Double-blind, placebo-controlled, randomized trial to determine the efficacy and safety of gemcabene on stable statin therapy	300, 900 mg (with various low, moderate and high intensity statins)	GEM=42 placebo=24	8 weeks	LDL-C, hsCRP, apoB, TG, HDL-C, VLDL, Total cholesterol
A4141001	Hypercholesterolemia (wash-out of statins)	Double-blind, placebo-controlled, randomized trial to determine the efficacy and safety of gemcabene as monotherapy or in combination with atorvastatin (after statin washout)	300, 600, 900 mg (with 10, 40, 80 mg atorvastatin)	GEM=208 atorvastatin=52 placebo=17	8 weeks	LDL-C, hsCRP, apoB, TG, HDL-C, Total cholesterol
A4141004	Osteoarthritis	Double blind, placebo controlled, randomized trial to determine the efficacy and safety of gemcabene in patients with osteoarthritis of the knee	150, 450, 900 mg (with rofecoxib 25 mg)	GEM=242 rofecoxib=79 placebo=83	4 weeks	Pain assessment, CGIC, PGIC, SODA

SODA=Sequential occupational dexterity assessment, PGIC=Patients global impression of change, CGIC=Clinical global impression of change, GEM=gemcabene; TG=triglycerides.

Gemcabene Phase 2 Trial in Patients with Hypercholesterolemia on Stable Statin Therapy (Trial 1027-018)

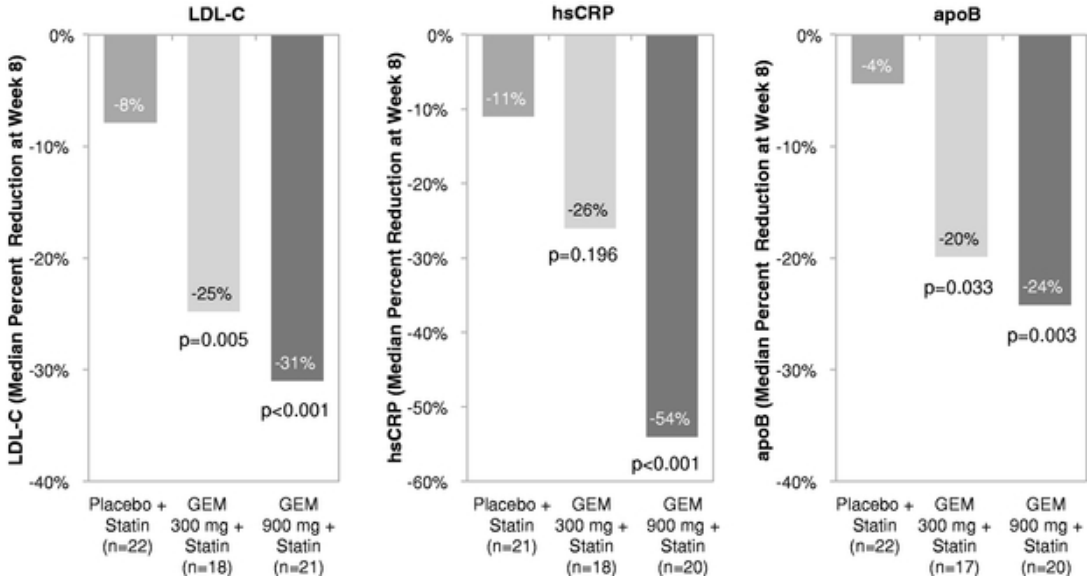
This Phase 2 double-blind, placebo-controlled, randomized trial in patients with hypercholesterolemia was designed to assess the efficacy and safety of gemcabene when added to stable statin therapy. Patients in this trial were on low (20% of patients), moderate (60% of patients) and high intensity (20% of patients) statin therapy. Gemcabene was administered at 300 mg and 900 mg once-daily for eight weeks. A majority of the patients were on moderate to high intensity statin therapy for at least three months. The primary endpoint was median percent change from baseline in LDL-C. Other endpoints included median perecent change from baseline in hsCRP, apoB, total cholesterol, VLDL-C and triglycerides at Week 8. A total of 66

patients were randomized and 61 patients were evaluated for efficacy. Baseline LDL-C levels were similar across the treatment arms at approximately 150 mg/dL.

Efficacy: As presented in the figure below, patients treated with gemcabene were observed to have significantly lowered LDL-C from baseline at 300 mg and 900 mg by 25% (p=0.005) and 31% (p<0.001), respectively. Of clinical interest, patients treated with gemcabene were observed to have significantly lowered hsCRP, apoB and total cholesterol. At 900 mg, patients treated with gemcabene were observed to have significantly lowered hsCRP by 54% (p<0.001). At 300 mg and 900 mg, patients treated with gemcabene were observed to have significantly lowered apoB by 20% (p=0.033) and 24% (p=0.003), respectively. At 300 mg and 900 mg, patients treated with gemcabene were observed to have significantly lowered total cholesterol by 18% (p=0.008) and 22% (p<0.001), respectively.

We believe these results support the continued development of gemcabene for the treatment HoFH, HeFH and ASCVD indications.

Median Percent Change from Baseline at Week 8 in Patients with Hypercholesterolemia on Background Stable Statin Therapy



LDL-C Median Percent Change from Baseline at Week 8 in Patients with Hypercholesterolemia on Background Stable Statin Therapy

	Placebo + Statin	GEM 300 mg + Statin	GEM 900 mg + Statin
n	22	18	21
Median Baseline LDL-C	153.3	143.5	142.5
Median Week 8 LDL-C	137	101.5	103
Median % Change	–7.9%	–24.8%	–31.0%
p-Value vs. Placebo	N/A	0.005	<0.001

*N/A = not applicable

Safety: Gemcabene was observed to be well tolerated. Patients taking either 300 mg or 900 mg of gemcabene were observed to have a safety profile similar to that of placebo. Slightly more patients experienced an associated AE in the placebo treatment arm (29%) than those in the gemcabene treatment arms (300 mg: 20%; 900 mg: 23%). One patient experienced an SAE in the gemcabene 900 mg treatment arm, which was not considered related to treatment. Three patients (placebo: 2, gemcabene 300 mg: 1) withdrew from the trial due to an AE, all of which were considered possibly related to treatment. AEs reported were generally mild to moderate in intensity. The most frequent AE in the placebo arm was infection (13%). The most frequent AEs in the gemcabene treatment arms were headache (10%) and infection (10%). There were no meaningful changes in liver enzymes ALT and AST. One patient in the 300 mg gemcabene treatment arm had an unverified rise in creatine kinase of 5 × upper limit of normal (ULN). No clinically meaningful changes in physical examinations or vital signs from baseline to the end of the trial were observed for any patient.

Gemcabene Phase 2 Trial in Patients with Hypercholestrolemia (Trial A4141001)

This Phase 2 double-blind, placebo-controlled, randomized trial was designed to assess the efficacy and safety of gemcabene administered as monotherapy, atorvastatin monotherapy or gemcabene in combination with atorvastatin in the treatment of patients with hypercholesterolemia. When applicable, patients were washed out of statins and other lipid-lowering therapies. Gemcabene was administered as monotherapy once-daily at 300 mg, 600 mg or 900 mg or in combination with atorvastatin once-daily at 10 gemcabene, 40 mg and 80 mg. The primary endpoint was percent change in LDL-C from baseline at Week 8. Secondary endpoints included percent change in hsCRP, apoB, HDL-C and triglycerides from baseline at Week 8. A total of 277 patients were randomized and 255 patients with at least one post baseline assessment were included in the efficacy analysis. Baseline LDL-C levels for the evaluable patients after washout were similar across treatment arms at approximately 175 mg/dL.

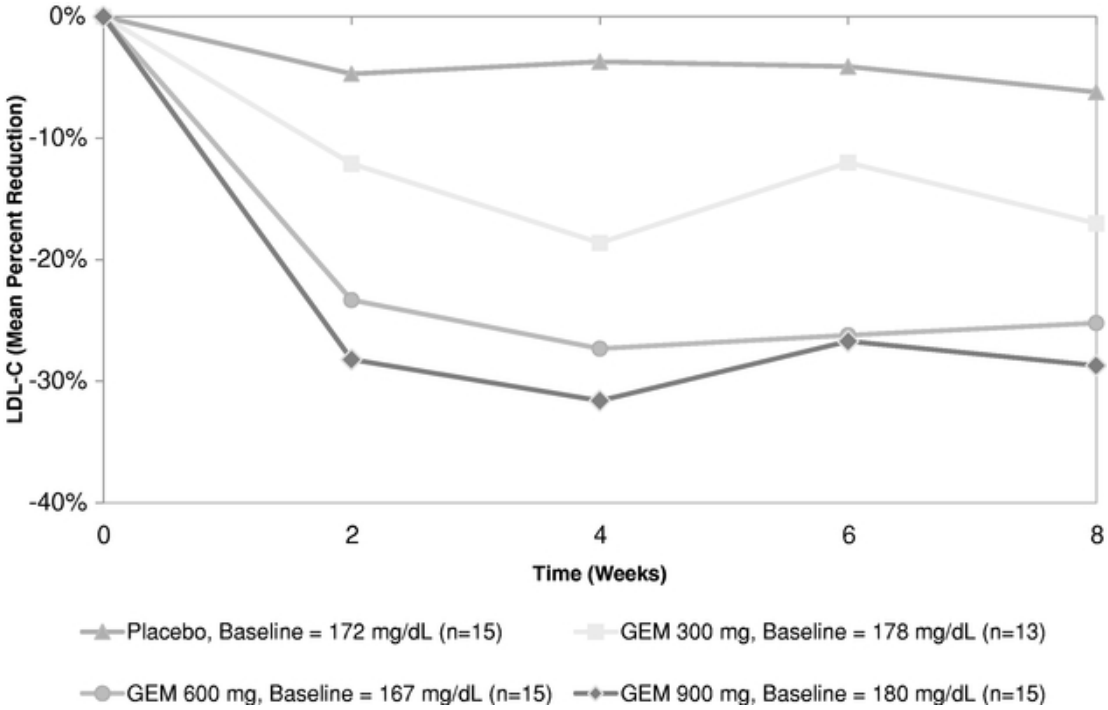
Efficacy: As presented in the figure below, patients treated with gemcabene were observed to have significantly lowered LDL-C by 17% (p=0.0013), 26% (p=0.0001) and 29% (p=0.0001) as monotherapy at 300 mg, 600 mg and 900 mg, respectively. The LDL-C lowering effect was seen within two weeks and was stable for the duration of the eight week trial. It is important to note that the patients included in this trial were statin responsive (able to reach goal near or below 100 mg/dL) at 10 mg, 40 mg and 80 mg atorvastatin monotherapy. While the trial demonstrated gemcabene provided additional dose dependent LDL-C lowering (statistically significant at 600 mg and 900 mg when compared to atorvastatin alone), the gemcabene treatment effect was less pronounced due to the patients already being at or below LDL-C goal of 100 mg/dL on atorvastatin monotherapy. Patients treated with gemcabene were observed to have lowered hsCRP by 26% (p=0.1612), 42% (p=0.0070) and 35% (p=0.0018) as monotherapy at 300 mg, 600 mg and 900 mg, respectively.

Patients treated with gemcabene in combination with atorvastatin aggregated over the dose range were observed to have mean LDL-C lowering of 50% (p=0.0852), 52% (p=0.0045) and 54% (p=0.0006) at 300 mg, 600 mg and 900 mg, respectively. Patients treated with gemcabene in combination with atorvastatin aggregated over the dose range were observed to have median hsCRP lowering of 47% (p=0.0237), 54% (p=0.0017) and 60% (p=0.0001) at 300 mg, 600 mg and 900 mg, respectively.

In a post-hoc analysis of patients with mixed dyslipidemia, we observed that gemacabene in combination with atorvastatin synergystically lowers triglyceride levels while further lowering LDL-C levels.

We believe these results support the continued development of gemcabene for the treatment HoFH, HeFH and ASCVD indications including mixed dyslipidemia.

LDL-C Mean Percent Change from Baseline in Patients with Hypercholesterolemia (with wash-out of statins)



Safety: Gemcabene was observed to be well tolerated. Patients taking any dose of gemcabene (300 mg, 600 mg or 900 mg) were observed to have a safety profile similar to that of atorvastatin monotherapy. A similar percentage of patients experienced an associated AE between atorvastatin monotherapy arms (14%) compared to gemcabene monotherapy (11%) and gemcabene plus atorvastatin treatment arms (17%). Three patients in the gemcabene plus atorvastatin arm experienced a SAE, none of which were considered related to treatment. 16 patients (placebo: 1, atorvastatin monotherapy: 2, gemcabene monotherapy: 6, gemcabene plus atorvastatin: 7) withdrew from the trial due to AEs, nine (atorvastatin monotherapy: 2, gemcabene monotherapy: 4, gemcabene plus atorvastatin: 3) of which were considered possibly related to treatment. AEs reported were generally mild to moderate in intensity. 14 patients (placebo: 1, atorvastatin monotherapy: 2, gemcabene monotherapy: 1, gemcabene plus atorvastatin: 10) reported an AE considered severe in intensity, one (gemcabene plus atorvastatin: 1) of which was considered possibly related to treatment. The most frequently occurring AEs across all treatment arms were infection (8%), pain (6%) and headache (6%). Two patients had ALT values that met the definition of a clinically important laboratory abnormality (placebo: 1, gemcabene 600 mg: 1). Small mean increases in serum creatinine and BUN were observed in the gemcabene monotherapy arms. One patient treated with 600 mg gemcabene plus atorvastatin had a clinically significant ALT elevation (>3 × ULN on two separate occasions) that returned to near normal levels while treatment continued. No other patient had a pre-specified clinically significant lab abnormality in ALT, AST, creatinine kinase or serum creatinine. No clinically meaningful changes in physical examinations or vital signs from baseline to the end of the trial were observed for any patient.

Gemcabene Phase 2 Trial in Patients with Elevated Triglycerides (Trial 1027-004)

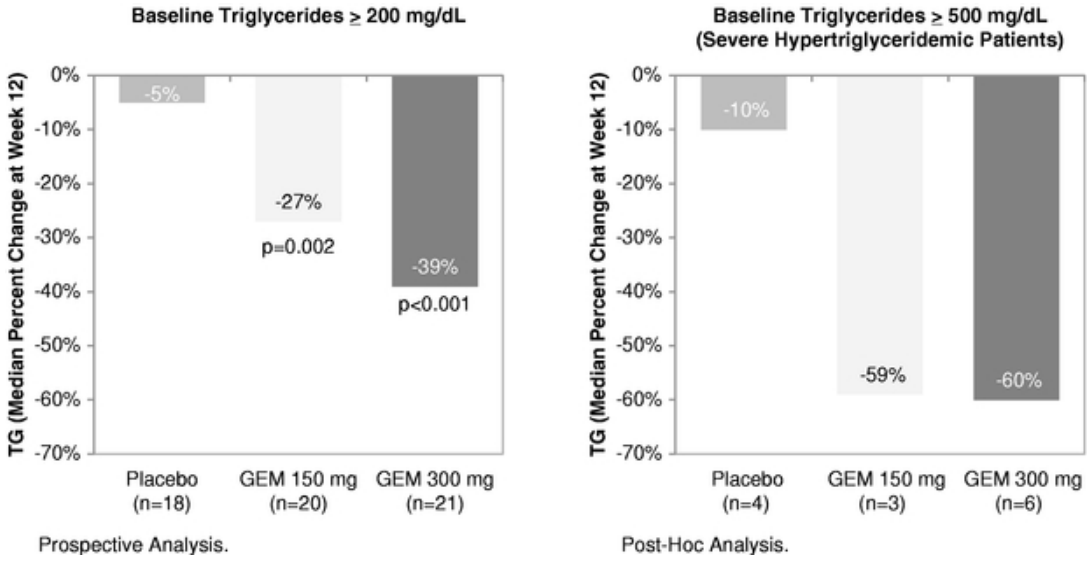
This Phase 2 double-blind, placebo-controlled, randomized trial was designed to assess the efficacy and safety of gemcabene in patients with low HDL-C and either normal or elevated triglycerides. Gemcabene was administered at 150, 300, 600 and 900 mg once-daily for 12 weeks. The objectives of this trial were to evaluate percentage change from baseline in HDL-C, LDL-C, triglycerides and other lipids and apolipoprotein variables at Week 12. A total of 161 patients were randomized. At baseline, 67 patients were normotriglyceridemic (<200 mg/dL) and 94 patients were hypertriglyceridemic (³200 mg/dL). Baseline triglycerides were approximately 370 mg/dL across the treatment arms with hypertriglyceridemia with the exception of the 600 mg treatment arm (580 mg/dL). A total of 155 patients (89 hypertriglyceridemic patients) had a post randomization assessment to be evaluated for efficacy. Baseline LDL-C levels for the evaluable patients, regardless of the triglyceride stratum, were similar across the treatment arms at approximately 110 mg/dL.

Efficacy: As presented in the figure below, patients with triglyceride levels greater than 200 mg/dL (hypertriglyceridemic patients), treated with gemcabene at 150 mg and 300 mg were observed to have lowered triglycerides by 27% (p=0.002) and 39% (p<0.001), respectively compared to baseline. Although patients treated with gemcabene at 600 mg and 900 mg were observed to have lower triglycerides, the lowering effect was not significant when compared to placebo. Therefore, the anticipated dose for treatment of patients with elevated triglyceride levels is 150 mg or 300 mg. Notably, patients treated with gemcabene were observed to have significantly lowered LDL-C by 19% (p<0.001) and 20% (p<0.001) at 600 mg and 900 mg, respectively, compared to baseline.

A post-hoc analysis of the nine patients with severe triglyceride levels (³500 mg/dL; baseline means of two weeks prior and time zero was approximately 600 mg/dL) treated with 150 mg and 300 mg suggest gemcabene has the potential to lower triglycerides by as much as 60%.

We believe these results support the continued development of gemcabene for the treatment SHTG and ASCVD patients with mixed dyslipidemia.

Triglyceride Median Percent Change From Baseline at Week 12 in Patients with High to Severe Hypertryglyceridemia



Safety: Gemcabene was observed to be well tolerated. Patients taking any dose of gemcabene (150 mg, 300 mg, 600 mg or 900 mg) were observed to have a safety profile similar to that of placebo. Fewer patients experienced an associated AE in the placebo arm (9%) compared to gemcabene treatment arms (17%). Three patients (placebo: 1, gemcabene: 2) experienced SAEs, none of which were considered related to treatment. Six patients (placebo: 2, gemcabene: 4) withdrew from the trial due to AEs, four (placebo: 1, gemcabene: 3) of which were considered possibly related to treatment. AEs reported were generally mild to moderate in intensity. Two patients (placebo: 1, gemcabene: 1) reported an AE considered severe in intensity. The most frequent AEs in the placebo arm were infection (16%), accidental injury (6%), back pain (6%), dyspepsia (6%), headache (6%) and sinusitis (6%). The most frequently observed AEs in the gemcabene arms were infection (12%), headache (7%) and asthenia (5%). Two patients had ALT values that met the definition of a clinically important laboratory abnormality (placebo: 1, 600 mg gemcabene: 1). One patient had elevated BUN values considered clinically significant (600 mg gemcabene: 1). All of these laboratory abnormalities were considered mild to moderate. No clinically meaningful changes in physical examinations or vital signs from baseline to the end of the trial were observed for any patient.

Gemcabene Phase 1 Clinical Trials

Gemcabene has been evaluated in ten completed Phase 1 trials in healthy volunteers. These trials explored safety, tolerability, pharmacokinetics, pharmacodynamics and dose response as monotherapy and in combination with high intensity statin doses and other drugs. The table below summarizes our completed Phase 1 trials.

Summary of Phase 1 Clinical Trials of Gemcabene in Healthy Volunteers

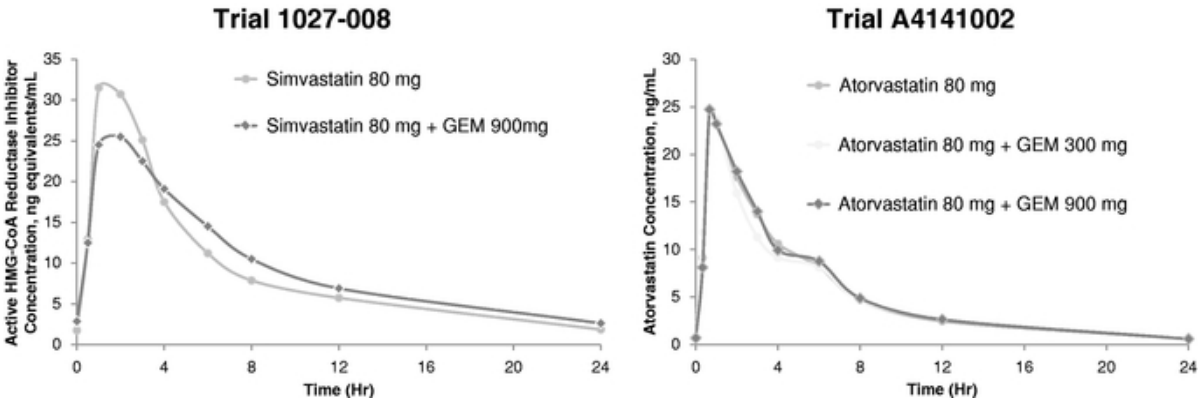
Trial Number	Trial Objectives	Doses	# Volunteers	Duration
1027-001	Single-dose trial to evaluate safety, tolerability and pharmacokinetics (PK) of gemcabene	25, 100, 300, 600, 1,050, 1,500 mg	GEM = 12	Single Dose
1027-002	Single-dose trial to evaluate the effect of food on the PK of gemcabene	450 mg	GEM = 12	Single Dose
1027-003	Double blind, placebo controlled, randomized trial to evaluate the PK and pharmacodynamics (PD) at multiple doses of gemcabene	50, 150, 450, 750/600, 900 mg	GEM = 40 placebo = 10	4 Weeks
1027-008	Trial to determine the potential drug-drug interactions of simvastatin with gemcabene	900 mg (with 80 mg simvastatin)	GEM = 20	15 Days
1027-009	Trial to evaluate the bioequivalence between a capsule and tablet formulation of gemcabene	300 mg	GEM = 16	Single Dose
1027-010	Trial to evaluate the mass balance and metabolism of gemcabene	600 mg	GEM = 6	Single Dose
1027-011	Trial to determine the potential drug-drug interactions of digoxin with gemcabene	900 mg (with 0.25 mg digoxin)	GEM = 12	10 Days
A4141002	Trial to determine the potential drug-drug interactions of atorvastatin with gemcabene	300, 900 mg (with 80 mg atorvastatin)	GEM = 20	22 Days
A4141003	Trial to evaluate the effect of gemcabene on QT interval	900 mg	GEM = 20	8 Days
A4141005	Trial to evaluate the effect of gemcabene on the glomerular filtration rate	900 mg (with 3,235 mg lohexol)	GEM = 12	10 Days

Note: One trial (A4141006; 23 volunteers) was stopped prior to completion as a result of discontinuation of the program. The trial was designed to evaluate multiple fixed-dose combinations of gemcabene with atorvastatin.

Gemcabene Phase 1 Drug-Drug Interaction Trials to Assess PK on Statins (Trials 1027-008 and A4141002)

Two open-label, multiple-dose, Phase 1 trials were conducted to assess PK of gemcabene in combination with high intensity statins. In Trial 1027-008, 900 mg of gemcabene was co-administered with 80 mg simvastatin in 20 healthy volunteers. In Trial A4141002, 300 mg and 900 mg of gemcabene were co-administered with 80 mg atorvastatin in 20 healthy volunteers. In both trials, treatment with gemcabene in combination with statins was observed to be well tolerated by volunteers. Furthermore, as presented in the figures below, the PK profiles with and without 900 mg gemcabene were observed to be similar, suggesting no clinically relevant drug-drug interactions with either 80 mg simvastatin or 80 mg atorvastatin.

PK Profiles of High Intensity Statins Co-administered with Gemcabene

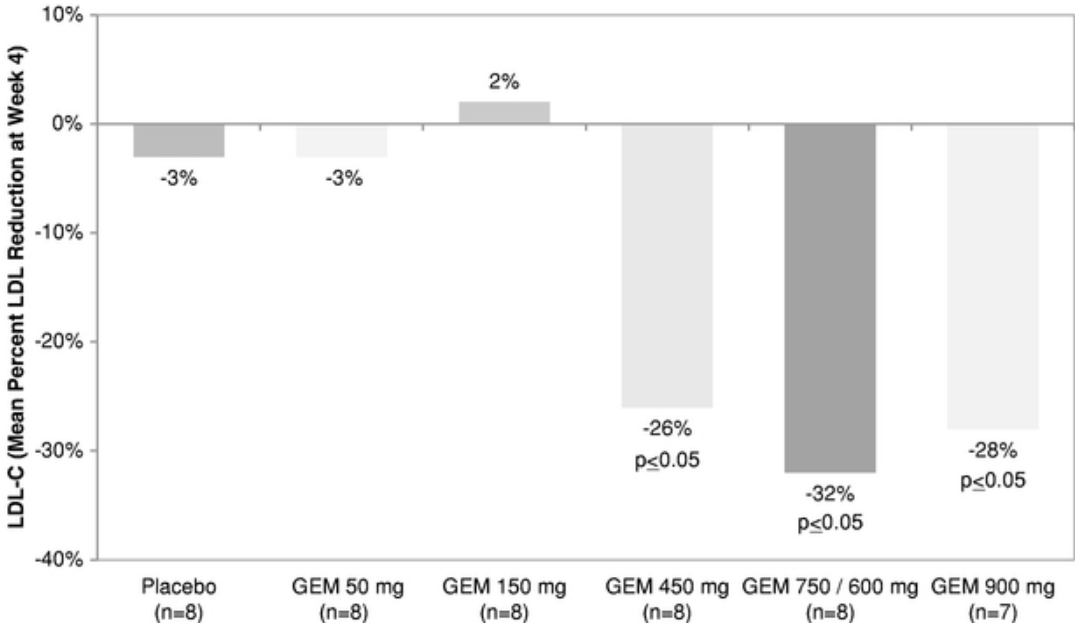


Gemcabene Phase 1 Dose Escalation Trial to Assess PK and PD (Trial 1027-003)

This Phase 1 randomized, double-blind, rising, multiple-dose trial was designed to assess PK characteristics and PD effect of gemcabene. Gemcabene was administered at doses ranging from 150 mg to 900 mg once-daily to 50 healthy volunteers over four weeks. Primary values measured were AUC(0-24) and Cmax. PD endpoints measured were total cholesterol, LDL-C, HDL-C, triglyercides, apoB and apoA1. Baseline LDL-C levels for the evaluable patients were similar across the treatment arms at approximately 120 mg/dL.

Efficacy: As presented in the figure below, volunteers treated with gemcabene were observed to demonstrate a dose response and significantly (p£0.05) lowered LDL-C by approximately 30% at 450 mg to 900 mg. Treated volunteers were observed to significantly (p£0.05) lower total cholesterol by 18% to 20% and apoB by 8% to 21% at 450 mg to 900 mg doses of gemcabene.

LDL-C Mean Percent Change from Baseline at Week 4 in Healthy Volunteers



Safety: Gemcabene was observed to be well tolerated. In general, frequency of AEs did not increase with dose. Healthy volunteers taking any dose of gemcabene (50 mg, 150 mg, 300 mg, 600/750 mg or 900 mg) were observed to have a safety profile similar to that of placebo. Slightly more patients experienced an associated AE in the placebo arm (60%) compared to those in the gemcabene treatment arms (40%). No patients experienced an SAE. One patient (placebo: 1) withdrew from the trial due to an AE. AEs reported were generally mild to moderate in intensity. Two patients (placebo: 1, gemcabene: 1) reported an AE considered severe. The most frequent AEs in the placebo arm were headache (60%), photosensitivity (20%), diarrhea (20%), skin and appendages (20%) and contact dermatitis (20%). The most frequent AEs in the gemcabene arms were headache (43%), infections (15%), asthenia (13%), photosensitivity (13%), nausea (15%) and rhinitis (13%). Mild elevations in BUN were observed, but overall, laboratory abnormalities were sporadic, transient, and appeared unrelated to gemcabene administration. No clinically meaningful changes in physical examinations or vital signs from baseline to the end of the trial were observed. No clinically significant ECG abnormalities were observed.

Gemcabene Preclinical Studies

As part of a comprehensive nonclinical toxicology program, over 30 exploratory and definitive single and repeated-dose toxicity studies with gemcabene were conducted in mice, rats, dogs and monkeys. There are very few outstanding nonclinical studies needed for registration such as two-year carcinogenicity studies in rodents and juvenile toxicology. Gemcabene was well tolerated in these completed studies, including a 26-week repeat dose study in rats and monkeys and 52-week repeat dose study in monkeys. The completed studies support conducting clinical trials up to six months.

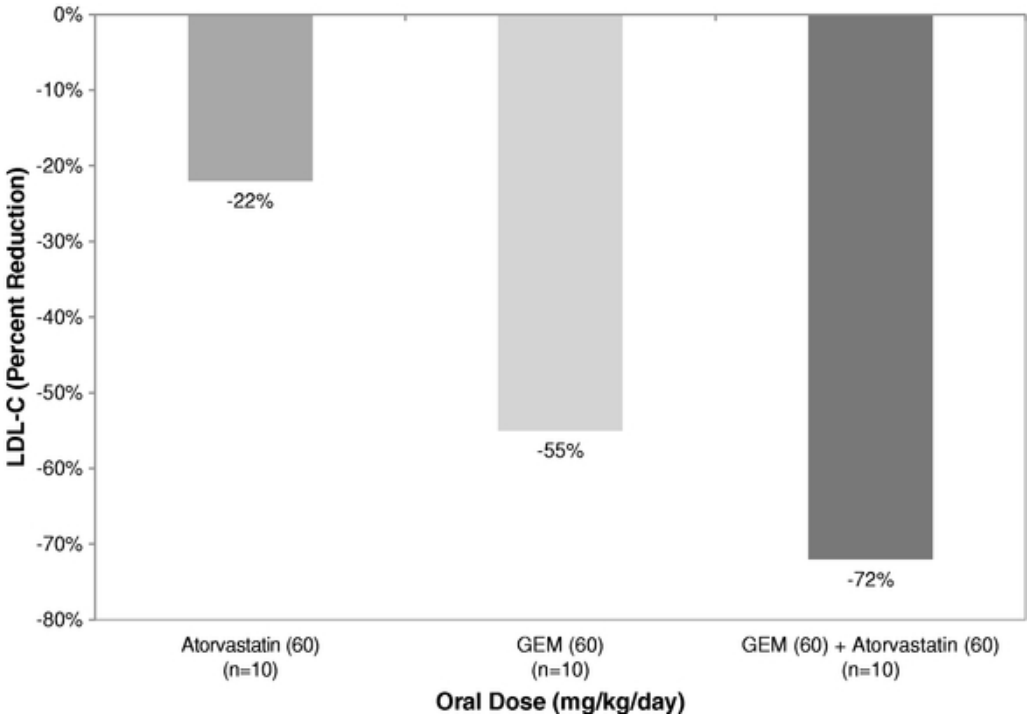
In multiple preclinical efficacy studies, gemcabene was observed to have lowering effects on plasma LDL-C, triglycerides and anti-inflammatory markers in diet-induced and genetic preclinical models of dyslipidemia.

In Vivo Proof of Principle Study for HoFH

In LDL-receptor deficient mice, gemcabene was observed to reduce LDL-C up to 55% as monotherapy and 72% in combination with statins. This LDL-receptor deficient animal model has been reported in literature

to be fairly predictive of HoFH therapies in practice. For example, statin lowering of approximately 20% in LDL-receptor deficient-mice model correlates well to the approximately 15% to 20% LDL-C lowering observed in HoFH patients, and Juxtapid lowering of approximately 50% to 80% in LDL-receptor deficient-rabbits model correlates well to the approximately 40% to 50% in HoFH patients.

Gemcabene Preclinical HoFH Mice Model



Gemcabene Clinical Development Plan

We plan to initiate three Phase 2b clinical trials in the first half of 2016 across our targeted indications. Upon completion of these clinical trials, we intend to request EOP2 meeting with the FDA and other foreign regulatory authorities to discuss the design and scope of the Phase 3 registration trials and long-term safety exposure needed for registration. We would expect to launch multiple Phase 3 registration trials in 2017 for our targeted indications. The development programs for our targeted indications are described below. We expect to conduct a few additional clinical pharmacology Phase 1 trials to support registration.

HoFH: COBALT-1 Trial (GEM-201)

The clinical development program for patients with HoFH with elevated LDL-C is expected to include one Phase 2b dose finding trial (GEM-201) followed by a Phase 3 registration trial. We expect to initiate the Phase 2b open-label, dose-escalation, dose-finding trial in patients with HoFH in the first half of 2016 in the United States and Canada. This trial is designed to evaluate the LDL-C lowering effect of gemcabene in a HoFH population at three doses. The trial is expected to enroll 8 to 10 patients with established clinical diagnosis of HoFH. Patients will be administered 300 mg, 600 mg or 900 mg doses at four to eight weeks each. The primary endpoint will be LDL-C lowering, the acceptable surrogate endpoint for approval in this population. Other endpoints will include hsCRP, apoB and total cholesterol. Safety of these patients will be assessed by AE monitoring, clinical laboratory assessments, ECGs, physical examinations and vital sign assessments. We expect to report top-line data for this Phase 2b trial by the end of 2016. The Phase 2b

trial is expected to provide the necessary data for us to determine the clinical dose for the Phase 3 registration trial. The Phase 3 registration trial (GEM-202, COBALT-2) is estimated to enroll 30 to 60 patients, and will be conducted globally with the potential for patients to continue in an open-label safety extension. It is anticipated that a single Phase 3 registration trial is expected to be sufficient to support registration.

Hypercholesterolemia ROYAL-1 Trial Gemcabene on Top of Maximum Tolerated Statins (GEM-301)

The clinical development program for patients with hypercholesterolemia (including but not limited to HeFH and ASCVD) with elevated LDL-C levels while on maximally tolerated statin therapy is expected to include one Phase 2b dose finding trial (GEM-301) followed by Phase 3 registration trials. We expect to initiate the Phase 2b double-blind, randomized, parallel-group, placebo-controlled, dose finding trial in patients with hypercholesterolemia on maximum statin therapy (with or without ezetimibe) in the first half of 2016 in the United States. This trial will be designed to evaluate the LDL-C lowering effect of gemcabene at three doses in combination with statins and/or ezetimibe. The trial is expected to enroll 100 to 200 patients with hypercholesterolemia on maximally tolerated statins where maximally tolerated statin therapy ranges from high intensity statin to no statin at all. Patients will be treated with 300 mg, 600 mg or 900 mg gemcabene once-daily for 8 to 12 weeks. The primary endpoint will be LDL-C lowering, the acceptable surrogate endpoint for approval in this population. Other endpoints will include hsCRP, apoB, and total cholesterol. Safety of these patients will be assessed by AE monitoring, clinical laboratory assessments, ECGs, physical examinations and vital sign assessments. We expect to report top-line data for this Phase 2b trial in the first half of 2017. Currently available data suggests 600 mg gemcabene would be the dose selected for the Phase 3 registration trial. After discussions with the FDA in our EOP2 meeting and other regulatory agencies, we believe we will be able to better define the Phase 3 registration trials and long-term safety exposure needed for registration.

SHTG: INDIGO-1 Trial (GEM-401)

The clinical development program for patients with SHTG with elevated triglyceride levels is expected to include one Phase 2b dose finding trial (GEM-401) followed by Phase 3 registration trial(s). We expect to initiate the Phase 2b double-blind, randomized, parallel-group, placebo-controlled, dose finding trial in patients with SHTG in the first half of 2016 in the United States. The trial will be designed to evaluate the triglyceride lowering effect. The trial is expected to enroll 120 to 150 patients with SHTG. Patients will be treated with 150 mg or 300 mg gemcabene at two dose levels of atorvastatin once-daily for 8 to 12 weeks. The primary endpoint will be triglyceride lowering and other endpoints will include LDL-C, hsCRP, apoB and total cholesterol lowering. A sub-analysis will be conducted to determine the number of patients at the end of the study achieving triglyceride levels below 500 mg/dL. Safety of these patients will be assessed by AE monitoring, clinical laboratory assessments, ECGs, physical examinations and vital sign assessments. We expect to report top-line data for this Phase 2b trial in the first half of 2017. The Phase 2b trial is expected to provide the necessary data for us to determine the clinical dose for the Phase 3 registration trials in patients with SHTG. After discussions with the FDA in our EOP2 meeting and other regulatory agencies, we believe we will be able to better define the Phase 3 registration trial(s) and long-term safety exposure needed for registration.

Additional Studies and Trials

Studies in Response to Partial Clinical Hold for Compounds in PPAR Class

In 2004, the FDA determined that gemcabene was a peroxisome proliferation-activated receptor (PPAR) agonist and as a result was subject to a partial clinical hold. The FDA has issued such notices to all sponsors of PPARs or agents deemed to have PPAR-like properties from preclinical studies. The partial clinical hold permits clinical trials of up to six months for gemcabene and also requires us to conduct two-year rat and mouse carcinogenicity studies before conducting clinical trials of longer than six months.

Our two-year rat and mouse carcinogenicity studies are scheduled for completion by the end of 2017 and draft reports will be issued several months thereafter.

The apparent weak PPARa effects observed in rodents (*e.g.*, peroxisome proliferation and elevation of liver weight), however, are rodent-specific phenomena, and, based on nonclinical and clinical experience, share little apparent relevance for human risk assessment. Furthermore, in PPAR agonist receptor binding assays we observed essentially no gemcabene binding to the mouse, rat, or human PPARa, PPARb, or PPARg receptors, whereas reference agents for each of the receptors showed the expected binding, including the marketed PPARa agents, such as fibrates, including gemfibrozil. We believe the PPARa responses in the rat are secondary and perhaps related to the mobilization or formation of a naturally occurring molecule that binds to PPARa in response to gemcabene administration.

Cardiovascular Outcome Trials

We believe it is well accepted that every 1.6 mg/dL lowering of LDL-C through the cholesterol synthesis pathway results in a 1% lowering of cardiovascular disease risk. The FDA has not required any approved therapy targeting LDL-C lowering, including non-statin therapies, to initiate or complete a cardiovascular outcome trial in connection with its approval of HoFH, HeFH and ASCVD. Based on recent drug approvals, we believe it is unlikely that the FDA will require us to initiate or complete a cardiovascular outcome trial for any of the above indications, although we would plan to initiate a cardiovascular outcome trial, for example in mixed dyslipidemia ASCVD patients, prior to NDA filing to pursue broader label indications related to cardiovascular disease risk reduction. Notwithstanding our current expectations, the FDA could require us to initiate or complete a cardiovascular outcome trial as a condition to filing or approving an NDA for gemcabene.

Sales and Marketing

Given our current stage of development, we have not yet established a commercial organization or distribution capabilities, nor have we entered into any partnership or co-promotion arrangements with an established pharmaceutical company. To develop the appropriate commercial infrastructure to launch gemcabene in the United States, if approved, for the narrower indications of HoFH, we may build out a specialty sales force to reach a concentrated number of approximately 50 lipid centers and 500 lipidologists across the country. This would require additional financial and managerial resources. We may engage in partnering discussions with third parties from time to time. When we seek approval and launch commercial sales of gemcabene outside of the United States or for broader patient populations in the United States, including patients with HeFH, ASCVD and SHTG, we may establish alliances with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related costs and our available resources.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on contract manufacturers to produce both the drug substance and drug product amounts required for our clinical trials and preclinical toxicology work. All lots of drug substance and drug product used in clinical trials are manufactured under current good manufacturing practices (cGMP), a quality system regulating manufacturing.

Gemcabene is a small molecule drug that can be synthesized as a crystalline monocalcium single polymorph with readily available raw materials and using conventional chemical processes.

Previous development has demonstrated the drug substance manufacture can be scaled up to 200 kg and drug product tablets can be manufactured at varying dosages. Previous stability data suggest an anticipated expiry of at least 18 months.

Gemcabene drug substance analytical development and production has been completed and scaled-up to meet commercialization cGMP requirements with sufficient chemistry, manufacturing, and control to support Phase 2b and Phase 3 trials. We have also selected a drug product manufacturer that has completed the analytical and process development to support the manufacture of tablets of various strengths, and which is currently manufacturing tablets to be used in our planned Phase 2b and Phase 3 clinical trials. We are also planning additional stability studies for both the drug substance and drug product lots manufactured in order to extend expiry and to support regulatory approval and commercial stage.

Our contract manufacturers are currently producing, and will produce in the future, our bulk drug substance and drug product for use in our preclinical studies and clinical trials utilizing reliable and reproducible synthetic processes and common manufacturing techniques. We obtain such supplies from manufacturers on a purchase order basis, and do not have any long-term arrangements. We intend to identify and qualify our current manufacturers as well as alternative manufacturers to provide bulk drug substance and drug product prior to the NDA submission to the FDA to ensure the regulatory support necessary for multiple manufacturing sites in order to supply sufficient commercial quantities at the drug launch and forward. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our drug substances and drug product candidates, if approved for marketing by the applicable regulatory authorities.

Pfizer License Agreement

In April 2011, we entered into a license agreement with Pfizer (the Pfizer Agreement) for a worldwide exclusive license to certain patent rights to make, use, sell, offer for sale and import the clinical product candidate gemcabene. In exchange for this license, we agreed to issue shares of our common stock to Pfizer representing 15% of our fully diluted capital at the close of the first arms-length series A financing, which occurred on March 31, 2015.

We agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first regulatory submission in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene or any product containing gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

We have also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales as specified in the Pfizer Agreement until expiration of the last valid claim of the licensed patent rights, including any patent term extensions or supplemental protection certificates. Under the Pfizer Agreement we are obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

The Pfizer Agreement will expire upon expiration of the last royalty term. Either party may terminate the Pfizer Agreement for the other party's uncured material breach and specified bankruptcy events. Pfizer may terminate the Pfizer Agreement if we or any of our sublicensees challenge the validity, enforceability or ownership of the licensed patents. Additionally, Pfizer may revoke the license if we are unable to adequately commercialize gemcabene by April 2021.

Intellectual Property

Our patent estate includes patents and/or patent applications to forms of gemcabene, methods of using gemcabene, and methods of manufacturing gemcabene. Charles Bisgaier, a co-founder of Gemphire, is an inventor on four of the six patent families. The active pharmaceutical ingredient and clinical formulations of the drug are protected by patents. Subsequent to obtaining the license from Pfizer, additional patents have been filed that are entirely owned by Gemphire.

As of August 25, 2015, Gemphire's patent estate, including patents we own or license from third parties, on a worldwide basis, included four issued U.S. patents, three pending U.S. patent applications and 20 issued patents in foreign jurisdictions including Canada, France, Germany, Great Britain, Ireland, Italy, Mexico and Spain and 15 pending patent applications in foreign jurisdictions including Australia, Canada, China, Europe, Hong Kong, Japan and Mexico. Of our worldwide patents and pending applications, all relate to our product candidate gemcabene.

U.S. Patent number 6,861,555, which was in-licensed from Pfizer, includes claims directed to the calcium salt crystal form of gemcabene that is used in our clinical formulations and will constitute the commercial product as well as other crystalline forms of gemcabene. This patent is expected to expire in 2021; however, we will likely select this patent for patent term extension from the U.S. Patent and Trademark Office (USPTO) if such an extension is available. Given the expected length of the regulatory review, the expiry date of this patent may be extended to 2023, or possibly 2024. Assuming market approval of gemcabene in 2019, data exclusivity would provide exclusivity for gemcabene out to about 2024. Furthermore, and importantly in our case, the FDA orphan designation for HoFH may provide us seven years of market exclusivity for gemcabene in the United States for HoFH. This market exclusivity would provide protection for gemcabene for treating HoFH out to about 2026. Related foreign patents, which have issued in jurisdictions including Canada, Denmark, Finland, France, Germany, Great Britain, Ireland, Italy, the Netherlands, Sweden, Spain, Japan, Mexico and New Zealand, are expected to expire in 2021, absent any adjustments or extensions.

U.S. Patent No. 8,557,835, which was also in-licensed from Pfizer, includes claims directed to pharmaceutical compositions comprised of combinations of gemcabene with statins and methods of using a combination of gemcabene and a statin for treating several conditions including hyperlipidemia. This patent is expected to expire in 2020, absent any extensions. Related foreign patents, which have issued in jurisdictions including France, Germany, Great Britain, Ireland, Italy, Spain, Mexico, and Singapore are expected to expire in 2018, absent any adjustments or extensions.

U.S. Patent No. 8,846,761, which is owned by Gemphire, includes claims directed to methods of reducing risk of pancreatitis with gemcabene treatment. This patent is expected to expire in 2032, absent any adjustments or extensions. Foreign counterpart patent applications are pending in Australia, Canada, China, Europe, Hong Kong, Mexico and Japan, and any patents issuing from such applications are expected to expire in 2031, absent any adjustments or extensions.

U.S. patent application number 14/370,722, which we own, is directed to methods of decreasing a patient's risk for developing coronary heart disease or preventing, delaying or reducing the severity of a secondary cardiovascular event by administering gemcabene with a statin. Related patent applications are pending in foreign jurisdictions including Australia, Canada, China, Europe, Japan and Mexico. Any patent that may issue in this family, absent any patent term adjustment or extension, is expected to expire in 2033.

As background, the patent term is typically 20 years from the date of filing a non-provisional application. In the United States, a patent's term may be lengthened several ways. First, patent term adjustment (PTA) compensates a patentee for administrative delays by the USPTO in granting a patent. Second, in certain instances, a patent term extension (PTE) can be granted to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, as provided under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. This restoration period cannot be longer than five years for approval of a drug compound, and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. Only one patent applicable to an approved drug is eligible for the PTE and the application for the extension must be submitted prior to the expiration of the patent and within 60 days from market approval. Independent of patent protection, in the United States, the Hatch-Waxman Act provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. Under this provision, gemcabene

may be eligible for up to five years of data and market exclusivity under the Hatch-Waxman Act, because it is considered a new chemical entity because the FDA has not previously approved any other drug containing the active ingredient of gemcabene. In Europe, under the Data Exclusivity Directive, pharmaceutical companies may receive up to 10 years to market their product without risk of competition.

Competition

Our industry is highly competitive and subject to rapid and significant innovation and change. The market for lipid regulating therapies is especially large and competitive. Our potential competitors include large pharmaceutical and biopharmaceutical companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Gemcabene, if approved, will face intense competition. Key competitive factors affecting its commercial success will include efficacy, safety, tolerability, reliability, convenience of dosing, price and reimbursement.

Statins are the most commonly used therapy to lower LDL-C in the dyslipidemia market. They are used by patients with HoFH as well as HeFH and ASCVD. Branded statins include AstraZeneca's Crestor (rosuvastatin), Merck's Zocor (simvastatin) and Pfizer's Lipitor (atorvastatin) among others. Generic statins are marketed by several companies including Apotex Inc., Mylan N.V. (Mylan), Dr. Reddy's Laboratories Ltd. and Lupin Pharmaceuticals, Inc. (Lupin) among others.

Non-statin based therapies are also used to lower LDL-C in dyslipidemia patients. Merck's Zetia (ezetimibe) is a common non-statin therapy that is often combined with statins for HoFH, HeFH and ASCVD patients. Merck's Vytorin and Liptruzet are fixed-dose combination therapies that combine ezetimibe with statins. Non-statin therapies are combined with statins to improve LDL-C lowering or to offer other efficacy benefits, including Daiichi Sankyo Inc.'s (Daiichi Sankyo) Welchol, a bile acid sequestrant and niacin. Non-statin therapies are also used to treat HoFH. These therapies include Aegerion's Juxtapid, a once-daily oral microsomal triglyceride transfer protein (MTP) inhibitor and ISIS Pharmaceuticals Inc. (ISIS) and Genzyme Corporation's, a Sanofi Company (Genzyme) Kynamro, a once-weekly injectable apoB antisense therapy. These agents have boxed warnings associated with liver toxicity and significant tolerability issues on their labels. Amgen's Repatha, an injectable PCSK9 inhibitor, was recently approved for HoFH, HeFH and ASCVD, and Sanofi's and Regeneron's PCSK9 inhibitor, Praluent, was recently approved for HeFH and ASCVD.

There are multiple product candidates in late stage development for HoFH, HeFH and ASCVD. CymaBay Therapeutic's (CymaBay) MBX-8025 (Phase 2) and Regeneron's RGEN-1500 (Phase 2) are in development for the treatment of HoFH. For hypercholesterolemia, including HeFH and ASCVD, drugs in development include oral cholesteryl ester transfer protein (CETP) inhibitors, Merck's anacetrapib (Phase 3) and Eli Lilly & Company's (Eli Lilly) evacetrapib (Phase 3), current Esperion's oral product, ETC-1002 (completed Phase 2), The Medicines Company/Alnylam Pharmaceuticals, Inc.'s (Alnylam) injectable PCSK9 inhibitor, ALN-PCS02 (completed Phase 1), and Pfizer's injectable PCSK9 inhibitor, bococizumab (Phase 3).

Fibrates, niacin and prescription fish oil are common therapies used to lower triglycerides in patients with severe hypertriglyceridemia. Examples of branded fibrates include Abbott Laboratories' Tricor and Trilipix, and an example of a branded niacin includes Niaspan, an extended-release niacin. In addition, AbbVie Inc. (AbbVie) markets combination therapies, such as Advicor (niacin extended release and lovastatin) and Simcor (niacin extended release and simvastatin). Prescribed generic versions of fibrates, such as gemfibrozil, are manufactured by many companies including Impax Laboratories, Inc. (Impax), Teva Pharmaceutical Industries Ltd. (Teva), Mylan and Lupin among others. Generic versions of niacins are manufactured by many companies including Teva, Lupin and Zydus Pharmaceuticals (USA), Inc., among others. Commonly used prescription fish oils include GlaxoSmithKline plc's (GlaxoSmithKline) Lovaza, AstraZeneca's Epanova and Amarin's Vascepa. Drugs that are in late stage development for SHTG include Trygg Pharma AS' (Trygg) AKR-963 (Phase 3), Acasti Pharma, Inc.'s (Acasti) CaPre (Phase 2), Catabasis

Pharmaceutical, Inc.'s (Catabasis) CAT-2003 (Phase 2) and Isis Pharmaceuticals, Inc.'s ISIS-APO-CIII (Phase 3).

Government Regulation

Government authorities at the federal, state and local level in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture (including any manufacturing changes), packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

United States — FDA Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act (FDC Act) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions by the FDA, including FDA refusal to approve pending NDAs, partial or full clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission of an investigational new drug application (IND) to the FDA, which must become effective before clinical trials may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of the FDA's pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical studies include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical studies must comply with federal regulations and requirements, including good laboratory practices, or GLP. The results of preclinical studies are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, available clinical data, and a proposed clinical trial protocol. Long term preclinical studies, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) in compliance with good clinical practice (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions if it believes that the clinical trial is either not being conducted in accordance with FDA

requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an IRB, for approval. An IRB must operate in compliance with FDA regulations. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap.

- § Phase 1 trials: The drug is initially introduced into healthy volunteers or patients, with the target disease or condition. The drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness.

- § Phase 2 trials: The drug is administered to a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, optimum dosage and to identify common adverse effects and safety risks.

- § Phase 3 trials: If the drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 trials, Phase 3 trials, including registration trials, are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 registration trials to demonstrate the efficacy of the drug. A single Phase 3 registration trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and, more frequently, if SAEs occur. Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within any specified period, or at all.

After completion of the required clinical trials, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all preclinical studies, clinical trials and other testing, a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls, and the proposed product labeling. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,374,000 for fiscal year 2016, and the manufacturer and/or applicant under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $114,000 per product and $585,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, diagnosis, or prevention of diseases or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain

late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it is compliant with cGMP, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. 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, or 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.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even 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, or require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval. As a condition of NDA approval, the FDA may also require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Elements to assure safe use can 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 requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably

likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Even if a product qualifies for this program, the FDA may later decide that the product no longer meets the conditions for qualification.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition — generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the

drug is safe and effective. The FDA may grant full or partial waivers for submission of data, as well as deferrals for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity — patent or non-patent — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Special Protocol Assessment

A company may reach an agreement with the FDA under the Special Protocol Assessment (SPA) process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. Under the FDC Act and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the clinical trial begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and FDA agree to the change in writing, or if the clinical trial sponsor fails to follow the protocol that was agreed upon with the FDA.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

AE reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredient in the same strength, route of administration and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical studies or clinical trials to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. 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 of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a drug containing a new chemical entity (NCE), which is a drug substance that contains an active moiety that has not been approved by the FDA in any other NDA, that moiety receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that moiety. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase — the time between IND application and NDA submission — and all of the review phase — the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Prescription Drug Marketing Act

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act (PDMA) imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

United States — Anti-Kickback, False Claims Laws and Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other statutes pertaining to health care fraud and abuse. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act (PPACA) amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to be in violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Violations of the Anti-Kickback Statute are punishable by penalties including imprisonment, criminal fines, civil monetary penalties, damages, disgorgement and exclusion from participation in federal healthcare programs.

Federal false claims laws, including the civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, PPACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act. The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the Civil Monetary Penalties Statute, which prohibits the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offerer/payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the healthcare fraud provisions of the Health Insurance Portability

and Accountability Act of 1996 (HIPAA), which prohibits knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations, or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

For example, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices undertaken by pharmaceutical companies, including off-label promotion, may violate false claims laws.

Pursuant to PPACA, the Centers for Medicare & Medicaid Services (CMS) has issued a final rule that requires manufacturers of certain prescription drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to collect and report information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The first reports were due in 2014 and must be submitted on an annual basis. The reported data were posted by CMS in searchable form on a public website on September 30, 2014, and will be posted on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual physicians in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws may face civil penalties.

Other federal and state requirements include the following:

- § HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the HITECH Act) and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- § 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

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

For example, in March 2010, PPACA was signed into law. PPACA has begun to, and will likely continue to, substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical industry. The Affordable Care Act, among other things: established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents; revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals

enrolled in Medicaid managed care organizations; implemented a new Medicare Part D coverage gap discount program; expanded the entities eligible for discounts under the Public Health Services pharmaceutical pricing program; created a new Patient Centered Outcomes Research Institute; and provided incentives to programs that increase the federal government's comparative effectiveness research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, 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.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, 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 drug 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.

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 drug under European Union regulatory systems, an applicant must submit a marketing authorization application (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 (EMA) is responsible for conducting the initial assessment of a drug. 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.

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 drug if such company can complete a full MAA with a complete database of pharmaceutical test, preclinical studies and clinical trials and obtain marketing approval of its product.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory

approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and adequate reimbursement for any product that might be approved for sale, we 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. Our product candidates may not be considered medically necessary or cost-effective. 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 or adequate reimbursement for the drug product. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the product candidates that we are developing and could adversely affect our net revenue and results.

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 product 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 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 health care costs in general, particularly prescription drugs, has become very 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. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, the emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the PPACA contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage status and adequate reimbursement level status are obtained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of August 31, 2015, we had eight employees, all of whom are full-time, two of whom hold Ph.D. or M.D. degrees, four of whom were engaged in research and development activities and four of whom were engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees is represented by a labor union or subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

We lease an approximately 1,450 square foot facility in Northville, Michigan that is primarily used for administrative and research and development activities. The lease commenced on January 1, 2015 and, as amended, expires on September 30, 2015. We are in the final stages of completing a lease for new facilities. We believe that these facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information regarding our current executive officers and directors as of August 31, 2015:

NAME	AGE	POSITION(S)
Executive Officers		
Mina Sooch[3]	47	President, Chief Executive Officer, Treasurer and Director
Charles L. Bisgaier	61	Chief Scientific Officer and Chairman of the Board
David Lowenschuss	47	Chief Legal Officer, Secretary and Director
Seth Reno	49	Chief Commercial Officer
Margaret McShane	51	Vice President of Clinical and Project Management
Carmen Daniela Oniciu	59	Vice President of Preclinical Research and Development and Manufacturing
Non-Employee Directors		
P. Kent Hawryluk[1][2]	46	Director
Kenneth Kousky[2][3]	61	Director
Andrew Sassine[1][2][3]	51	Director

(1) Member of the compensation committee.

(2) Member of the audit committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Mina Sooch has served as our President and Chief Executive Officer and as a member of our board of directors since November 2014. Prior to joining the Company, she served from July 2012 to May 2014 as the President and Chief Executive Officer of ProNAi Therapeutics, Inc., a public clinical-stage oncology company, and as a member of the board of directors from its founding in 2004 through May 2014 as well as a business development advisor from December 2010 to June 2012. In addition, Ms. Sooch founded Apjohn Ventures Fund, a venture capital firm that invests primarily in early-stage life sciences companies, and has served as its Managing Partner since its founding in 2003. She also serves as Manager of Tara Ventures I, LLC, an angel fund organized in 2002, for life sciences investments. Ms. Sooch also served as an entrepreneur in residence at North Coast Technology Investors LP from 2001 to 2002. Ms. Sooch co-founded three life sciences start-ups: ProNAi Therapeutics, Inc., Afmedica, Inc. and CytoPherx Inc. (formerly known as Nephrion Inc.). Ms. Sooch has served on over 10 private, public and non-profit venture capital boards including ProNAi Therapeutics, Inc., ZyStor Therapeutics, Inc., Asterand Inc., CytoPherx Inc., Svelte Medical Systems, Inc., Wolverine Venture Fund and Michigan Venture Capital Association. From 1993 to 2000, she last served as global account manager at Monitor Deloitte (formerly known as Monitor Company Group), a global strategy consulting firm based in Boston. Ms. Sooch received an M.B.A. from Harvard Business School and a B.S. in chemical engineering from Wayne State University. Our board of directors believes Ms. Sooch should serve as a director based on her extensive experience founding and developing biopharmaceutical companies and managing and negotiating venture capital investments and strategic transactions.

Dr. Charles Bisgaier, one of our co-founders, has served as our Chief Scientific Officer and Chairman of our board of directors since November 2014. He also currently serves as an Adjunct Associate Professor of Pharmacology at the University of Michigan. Prior to our founding, he served from September 2008 to November 2014 as the Chief Executive Manager for our predecessor, Michigan Life Therapeutics, LLC. In addition, he co-founded Michigan Life Ventures, LLC, a venture capital firm investing primarily in Michigan-based life sciences companies, where since 2008 he has served as the Chief Executive Manager. He also served as the Interim President and Chief Executive Officer of ProNAi Therapeutics, Inc., a clinical-stage oncology company, from September 2010 to April 2012, and as a member of its board of directors from 2009 to March 2014. In 1998, Dr. Bisgaier co-founded the original Esperion, which was acquired by Pfizer in 2003. After the acquisition, he served as the Senior Director of Pharmacology for the Esperion Division of Pfizer Global Research and Development from 2004 to 2006. From 2006 to 2008, Dr. Bisgaier also served as a director, board member and president of Pipex Pharmaceuticals, Inc., currently known as Synthetic Biologics, Inc., a specialty pharmaceutical company. From 1990 to 1998, Dr. Bisgaier was an Associate Research Fellow in the Department of Cardiovascular Diseases in the Parke-Davis division of Warner-Lambert Co. Currently he is a board member at Hygieia, Inc., a privately held health service company, and at BioSavita Inc., a privately held life sciences company. He received a B.A. in biology from the State University of New York at Oneonta and an M.S. and Ph.D. in biochemistry from George Washington University. After receiving his Ph.D., he studied lipoprotein metabolism within the Specialized Center of Research for atherosclerosis at Columbia University College of Physicians and Surgeons. Our board of directors believes Dr. Bisgaier should serve as a director based on his depth of experience in founding and developing biopharmaceutical companies as well as his knowledge of our product candidate gemcabene.

David Lowenschuss, one of our co-founders, has served as our Chief Legal Officer and as a member of our board of directors since November 2014. From 2008 to present, Mr. Lowenschuss has had a private legal practice (David H. Lowenschuss PLC) where he acts as counsel to a number of life science companies. Mr. Lowenschuss also co-founded Michigan Life Ventures, LLC and currently serves as its Chief Legal Manager. In 2008, Mr. Lowenschuss co-founded Michigan Life Therapeutics, LLC, where he served as Chief Legal Manager from 2008 to November 2014. Mr. Lowenschuss served as Corporate Counsel and later Michigan Legal Site Head at Pfizer, a public biopharmaceutical company, from 2004 to 2008. Prior to joining Pfizer, from 2001 to 2004, Mr. Lowenschuss was in-house counsel at the original Esperion. Mr. Lowenschuss has lectured at the University of Michigan on various topics including historical perspectives on human subject research and also serves as a moot court judge at the University of Michigan Law School. He holds a J.D. from George Washington University and an M.U.P. and a B.A. from the University of Michigan. He is admitted to practice law in Michigan. Our board of directors believes Mr. Lowenschuss should serve as a director based on his strategic partnering abilities as well as his knowledge and vast experience in the biopharmaceutical industry.

Seth Reno has served as our Chief Commercial Officer since August 2015. Prior to joining us, he served in several commercial roles including Head of Commercial Operations for Medimmune, LLC, a biologics company, from June 2010 to April 2015. From April 2001 to June 2010, Mr. Reno worked at AstraZeneca, a public biopharmaceutical company, in a number of roles, including in the sales, commercial operations, managed markets and brand team spaces. Prior to joining AstraZeneca in 2001, Mr. Reno spent 11 years at Wyeth Pharmaceuticals, Inc., a pharmaceutical company, in commercial operations and sales account management. Mr. Reno holds a B.S. in human resources from the University of Delaware and an M.B.A. from Strayer University.

Margaret McShane has served as our Vice President of Clinical and Project Management since November 2014. Since 2008, Ms. McShane has been an independent consultant providing consulting services to many pharmaceutical companies, including our predecessor, Michigan Life Technologies, LLC. In addition, from March 2010 to April 2012, she was Director of Clinical Research at Hygieia Research, LLC, a medical device company. From 2007 to 2008, Ms. McShane was Vice President of Clinical Development at Pipex

Pharmaceuticals, Inc., a specialty pharmaceuticals company. From 1986 to 2006, she held various positions at Pfizer, including Director of Operations, Pfizer Global Research and Development Cardiovascular Research, Director of Transition Management, Pfizer Global Research and Development and Manager of Clinical Operations Medical Development. Ms. McShane holds a B.S. in chemistry and biology from Adrian College and an M.B.A. from Western Michigan University.

Dr. Daniela Oniciu has served as our Vice President of Preclinical Research and Development and Manufacturing since November 2014. Prior to joining us, Dr. Oniciu worked as an independent consultant focused on preclinical research and development and regulatory affairs related to chemistry, manufacturing and controls for pharmaceuticals and fine chemicals that span small molecules. Prior to that, from 2006 to February 2014, Dr. Oniciu served as Senior Director of Chemistry at Cerenis Therapeutics Holding SA, a French biotechnology company. Prior to joining Cerenis, from 2001 to 2004, Dr. Oniciu was Senior Director of Chemical Research and Development at the original Esperion, where she served as co-chair of the preclinical research team. Following Pfizer Inc.'s acquisition of the original Esperion, Dr. Oniciu served as Associate Director of Chemistry at Pfizer from 2004 to 2005. Prior to joining the original Esperion in 2001, Dr. Oniciu co-founded Alchem Laboratories Corporation, a custom research organization that specialized in drug design and process development support for the pharmaceutical industry. In addition, Dr. Oniciu has served as Courtesy Professor of Chemistry at the University of Florida at Gainesville since 2004. Dr. Oniciu holds a Ph.D. and an M.S. in organic chemistry and chemical engineering, both from the Polytechnic University of Bucharest in Romania.

Non-Employee Directors

P. Kent Hawryluk has served as a member of our board of directors since February 2015. He is the Co-Founder and has served as the Chief Business Officer of Avidity NanoMedicines LLC, a precision nanomedicines company, since January 2013. He is also Co-Founder and has served as the Chief Executive Officer of MB2 LLC, a clinical-stage company focused on diabetes and obesity, since May 2014. In January 2006, Mr. Hawryluk co-founded Marcadia Biotech Inc., which was acquired by Roche Holding Ltd., where he served as Chief Business Officer and Vice President, Business Development from January 2006 to April 2011. He currently serves as partner of Twilight Venture Partners, LLC, a private seed and early-stage life science venture capital fund. He was a founding partner of JEGI Capital, LLC, a venture capital fund co-sponsored by GE Capital Corp. that launched in 2000. Mr. Hawryluk holds a B.A. from Princeton University, an M.B.A. from Kellogg School of Management at Northwestern University, and an M.S. degree in biology from Indiana University-Purdue University Indianapolis. Our board of directors believes Mr. Hawryluk should serve as a director based on his experience founding and developing biopharmaceutical companies and his knowledge of the biopharmaceutical industry.

Kenneth Kousky has served as a member of our board of directors since March 2015. Mr. Kousky has also served as the Chief Executive Officer of the Mid-Michigan Innovation Center, a privately funded, non-profit business incubator, since 2010. He has also served as the President and Chief Executive Officer of IP3, Inc., an information security consulting firm, since 2002. Also, Mr. Kousky is a founding member and has served as Executive Director of the Blue Water Angels Investment Network, a Michigan-based funding network that assists in private equity investments in early-stage tech startups, since 2008. In 1988, Mr. Kousky founded an IT services company, Wave Technologies International Inc., which he led through an initial public offering in 1994. In 1989, he established Washington University's graduate program in Telecommunication Management, and he has lectured at Saginaw Valley State University, Washington University and at the Wharton School of Business at the University of Pennsylvania. Mr. Kousky is a member of several corporate boards, including Michigan Sugar Corporation, RetroSense Therapeutics LLC and Foodjunky LLC. Mr. Kousky holds a B.A. in economics and urban studies from Washington University, and an M.S. in economics from University of Pennsylvania. Our board of directors believes Mr. Kousky should serve as a director based on his extensive financial and strategic business planning experience.

Andrew Sassine has served as a member of our board of directors since May 2015. Mr. Sassine served in various positions at Fidelity Investments from 1999 to 2012, including as a Portfolio Manager for various funds from 2005 to 2012. Mr. Sassine has also served on several boards of life science companies. Mr. Sassine currently serves on the board of directors of FluoroPharma Medical, Inc., a public biopharmaceutical company, and CNS Response, Inc., a public psychiatric clinical decision support company. Mr. Sassine also serves on the board of directors of MD Revolution Inc., a private digital health service company, Freedom Meditech, Inc., a private medical device company, and Comhear Inc., a private digital audio software and device company, where he is also the chairman of the board of directors. Mr. Sassine has been a member of the Henry B. Tippie College of Business, University of Iowa Board of Advisors since 2009 and served on the board of trustees at the Clarke Schools for Hearing and Speech from 2009 through 2014. Mr. Sassine holds a B.A. from the University of Iowa and an M.B.A. from the Wharton School at the University of Pennsylvania. Our board of directors believes Mr. Sassine should serve as a director based on his extensive experience in the public markets as well as his financial expertise.

Board Composition

The voting agreement entered into in connection with the closing of our Series A convertible preferred stock financing provides for two directors to be elected by the holders of a majority of our common stock, voting as a single class; two directors to be elected by the holders of a majority of our common stock and Series A convertible preferred stock, voting collectively as a single class; and one director to be elected by the holders of our Series A convertible preferred stock, voting as a single class, who is designated as Mr. Kousky. Moreover, under the voting agreement entered into in connection with the incorporation of Gemphire, the parties thereto agreed to vote their shares so as to elect three directors designated initially as Dr. Bisgaier, Mr. Lowenschuss and Ms. Sooch. The voting agreements by which our directors were elected will terminate in connection with this offering and there will be no continuing contractual obligations regarding the election of our directors. Each of our current directors will continue to serve until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

Our business and affairs are organized under the direction of our board of directors. The board of directors currently consists of six members with one vacancy and, effective as of the closing of this offering, will consist of members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors, except Ms. Sooch, Dr. Bisgaier and Mr. Lowenschuss, are independent directors, as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules.

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective immediately prior to the consummation of this offering, our board of directors will be divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms.

Effective upon the closing of this offering, our board of directors will be comprised of the following classes:

- Class I, which will consist of , whose terms will expire at our annual meeting of stockholders to be held in 2016;
- Class II, which will consist of , whose terms will expire at our annual meeting of stockholders to be held in 2017; and
- Class III, which will consist of , whose terms will expire at our annual meeting of stockholders to be held in 2018.

Each director's term continues until the election and qualification of his successor, or his earlier death, resignation, or removal. Our amended and restated certificate of incorporation and amended and restated bylaws, which will be in effect immediately prior to the consummation of this offering, will authorize only

our board of directors to fill vacancies on our board of directors. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company. See "Description of Capital Stock — Anti-Takeover Provisions."

Board Leadership Structure

Our board of directors is currently chaired by our Chief Scientific Officer, Dr. Bisgaier, who has authority, among other things, to call and preside over meetings of our board of directors, to set meeting agendas and to determine materials to be distributed to the board of directors and, accordingly, has substantial ability to shape the work of the board of directors. The positions of our chairman of the board and Chief Executive Officer are presently separated. Separating these positions allows our Chief Executive Officer, Ms. Sooch, to focus on our day-to-day business, while allowing, Dr. Bisgaier, our co-founder who was also instrumental in the discovery and development of gemcabene, to lead the board of directors.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee is currently comprised of Mr. Kousky, Mr. Hawryluk and Mr. Sassine and Mr. Kousky is currently the chairman. Following the closing of this offering, our audit committee will consist of , and and will serve as chairman of the committee. Each member of our audit committee meets the requirements for independence under the current NASDAQ and SEC rules and regulations and is financially literate. In addition, our board of directors has determined that is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements;
- our compliance with legal and regulatory requirements;

- the qualifications, independence and performance of our independent auditors; and
- the preparation of the audit committee report to be included in our annual proxy statement.

Compensation Committee

Our compensation committee is currently comprised of Mr. Hawryluk and Mr. Sassine and Mr. Hawryluk is currently the chairman. Following the closing of this offering, our compensation committee will consist of and and will serve as chairman of the committee. Each member of our compensation committee meets the requirements for independence under the current NASDAQ and SEC rules and regulations, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1984, as amended, or the Code, and is a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer and director compensation arrangements, plans, policies and programs;
- administering our cash-based and equity-based compensation plans; and
- making recommendations to our board of directors regarding any other board of director responsibilities relating to executive compensation.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is currently comprised of Mr. Sassine, Mr. Kousky and Ms. Sooch. Following the closing of this offering, our nominating and corporate governance committee will consist of , and and will serve as chairman of the committee. Each member of our nominating and corporate governance committee, other than Ms. Sooch, meets the requirements for independence under the current NASDAQ and SEC rules and regulations. As of the closing of this offering, we expect that the nominating and corporate governance committee will comply with the applicable rules and regulations of the NASDAQ and SEC. Our nominating and corporate governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

Compensation Committee Interlocks and Insider Participation

We have established a compensation committee, which has and will make decisions relating to compensation of our executive officers. None of the directors serving on the compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Limitation on Liability and Indemnification of Directors and Officers

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering, limit our directors' liability to the fullest extent permitted under Delaware corporate law. Delaware corporate law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any transaction from which the director derives an improper personal benefit;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (unlawful payment of dividends or redemption of shares); or

- for any breach of a director's duty of loyalty to the corporation or its stockholders.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as one of our directors or officers or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation and amended bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

Executive Officer Compensation

The following tables and accompanying narrative disclosure discuss the compensation awarded to, earned by, or paid to:

- Mina Sooch, our President, Chief Executive Officer, Treasurer and Director;
- Charles L. Bisgaier, Ph.D., our Chief Scientific Officer and Chairman of our Board of Directors; and
- David Lowenschuss, our Chief Legal Officer, Secretary and Director.

We refer to these three executive officers as the "named executive officers."

2014 Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was earned by our named executive officers during the fiscal year ended December 31, 2014.

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)[1]	STOCK AWARDS ($)[2]	TOTAL ($)
Mina Sooch *President, Chief Executive Officer and Treasurer*	2014	—	56,000	56,000
Charles L. Bisgaier, Ph.D. *Chief Scientific Officer*	2014	—	20,832	20,832
David Lowenschuss *Chief Legal Officer and Secretary*	2014	—	27,776	27,776

(1) We did not pay a salary, bonus, non-equity incentive plan compensation or any other cash compensation to any of our named executive officers during the year ended December 31, 2014. As discussed further below, we entered into employee agreements with our named executive officers in November 2014 that provided for grants of restricted stock during the fiscal year ended December 31, 2014 and salary payments commencing January 1, 2015.

(2) The amounts reported do not reflect the amounts actually received by our named executive officers. Instead, these amounts reflect the aggregate grant date fair value of each equity award granted to our named executive officers during the fiscal year ended December 31, 2014, as computed in accordance with FASB ASC 718. Assumptions used in the calculation of these amounts are included in Note 9 to our financial statements included in this prospectus. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions.

Agreements with Our Named Executive Officers

We have entered into written employee agreements setting forth the terms and conditions of employment for each of our named executive officers, as described below. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see "— Potential Payments Upon Termination or Change of Control" below.

Each of our named executive officers has also executed our standard form of confidential information and invention assignment agreement.

Employment Agreement with Mina Sooch

In November 2014, we entered into an employee agreement with Ms. Sooch that, as amended in June 2015, governs the terms of her employment with us. Under the terms of the employee agreement, Ms. Sooch is entitled to an annual base salary of $350,000 beginning on January 1, 2015. Ms. Sooch agreed to defer 20% of her salary until June 30, 2015, to be paid in cash or stock at Ms. Sooch's election. In June 2015, we granted her a fully-vested stock option exercisable for 16,280 shares of our common stock, at an exercise price equal to $0.431 per share, in satisfaction of our obligations under such deferral arrangement. Pursuant to the employee agreement, Ms. Sooch was granted 2,000,000 shares of common stock, with 1,000,000 shares vesting immediately and the other 1,000,000 shares vesting in 24 equal monthly installments at the end of each month beginning in November 2014, subject to continued service. Upon the completion of this offering, all such shares will fully vest. Ms. Sooch is additionally entitled to certain severance benefits pursuant to her employee agreement, the terms of which are described under "— Potential Payments Upon Termination or Change of Control."

Employment Agreement with Charles L. Bisgaier, Ph.D.

In November 2014, we entered into an employee agreement with Dr. Bisgaier that, as amended in April and June 2015, governs the terms of his employment with us. Under the terms of the employee agreement, Dr. Bisgaier is entitled to an annual base salary of $300,000 beginning on January 1, 2015. Dr. Bisgaier agreed to defer 20% of his salary until June 30, 2015, to be paid in cash or stock at Dr. Bisgaier's election. In June 2015, we granted him a fully-vested stock option exercisable for 13,954 shares of our common stock, with an exercise price equal to $0.431 per share, in satisfaction of our obligations under such deferral arrangement. In connection with the merger with MLT, we agreed to issue to Dr. Bisgaier 3,720,000 shares of our common stock, of which 2,976,000 shares were fully vested on the date of grant and 744,000 shares vest in 18 equal monthly installments at the end of each month beginning in November 2014, subject to continued service. Upon the completion of this offering, all such shares will fully vest. Dr. Bisgaier is additionally entitled to certain severance benefits pursuant to his employee agreement, the terms of which are described below under "— Potential Payments Upon Termination or Change of Control."

Employment Agreement with David Lowenschuss.

In November 2014, we entered into an employee agreement with Mr. Lowenschuss that, as amended in April and June 2015, governs the terms of his employment with us. Under the terms of the employee agreement, Mr. Lowenschuss is entitled to an annual base salary of $240,000, on a full-time basis, to be adjusted to reflect Mr. Lowenschuss's reduced schedule. From January 1 through March 31, 2015, Mr. Lowenschuss's work schedule was 20 hours per week, which increased to 32 hours per week as of April 1, 2015. Mr. Lowenschuss agreed to defer 20% of his salary until June 30, 2015 to be paid in cash or in stock at Mr. Lowenschuss's election. In June 2015, we granted him a fully-vested stock option exercisable for 7,256 shares of our common stock, with an exercise price equal to $0.431 per share, in satisfaction of our obligations under such deferral arrangement. In connection with the merger with MLT, we agreed to issue to Mr. Lowenschuss 2,480,000 shares of our common stock, of which 1,488,000 shares were fully vested on the date of grant and 992,000 shares vest in 18 equal monthly installments at the end of each month beginning in December 2014, subject to continued service. Upon the completion of this offering, all such shares will fully vest. Mr. Lowenschuss is additionally entitled to certain severance benefits pursuant to his employee agreement, the terms of which are described below under "— Potential Payments Upon Termination or Change of Control."

We intend to enter into new employment agreements with certain senior management personnel in connection with this offering. We expect that each of these agreements will provide for at-will employment and include each named executive officer's base salary, a discretionary annual incentive bonus opportunity and standard employee benefit plan participation. We also expect these agreements to provide for severance benefits upon termination of employment or a change in control of our company.

Potential Payments Upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, the named executive officer is entitled to receive amounts earned during his or her term of service, including salary and unused vacation pay. In addition, each of our named executive officers is eligible to receive certain benefits pursuant to his or her agreement with us described above under "— Agreements with our Named Executive Officers."

If Ms. Sooch's employment is terminated without cause, she would be entitled to receive severance payments equal to continued payment of her base salary for twelve months. Further, if Ms. Sooch is terminated without cause, or we are acquired or merged or complete an initial public offering, then Ms. Sooch's unvested equity award shall vest automatically in full.

If Dr. Bisgaier's employment is terminated without cause, he would be entitled to receive severance payments equal to continued payment of his base salary for twelve months. Further, if Dr. Bisgaier is terminated without cause, or we are acquired or merged or complete an initial public offering, then Dr. Bisgaier's unvested equity award shall vest automatically in full.

If Mr. Lowenschuss's employment is terminated without cause, he would be entitled to receive severance payments equal to continued payment of his base salary for six months. Further, if Mr. Lowenschuss is terminated without cause, or we are acquired or merged or complete an initial public offering, then Mr. Lowenschuss's unvested equity award shall vest automatically in full.

Outstanding Equity Awards at Fiscal Year-End

No named executive officer was granted any stock options prior to January 1, 2015. The following table sets forth information regarding restricted stock awards and outstanding stock options held by our named executive officers as of December 31, 2014:

		STOCK AWARDS[1]		
NAME	GRANT DATE	VESTING COMMENCEMENT DATE	NUMBER OF SHARES THAT HAVE NOT VESTED (#)	MARKET VALUE OF SHARES THAT HAVE NOT VESTED ($)[2]
Mina Sooch	November 1, 2014	November 1, 2014	916,667[3]	61,417
Charles L. Bisgaier, Ph.D.	November 1, 2014	November 1, 2014	661,333[4]	44,309
David Lowenschuss	November 1, 2014	December 1, 2014	936,889[5]	62,772

(1) Unless otherwise noted, all of the shares of restricted stock were granted prior to our adoption of the 2015 Plan and under an employee agreement with each named executive officer, the terms of which employee agreements are described above under "— Agreements with our Named Executive Officers."

(2) Market value is calculated by multiplying the number of shares that were unvested as of December 31, 2014 by $0.067, which was the fair market value of one share of our common stock on December 31, 2014 as determined by our board of directors.

(3) Subject to a 24-month vesting schedule, vesting monthly in equal increments over the remaining 22-month period. The awards are also eligible for accelerated vesting on the closing of this offering, a qualifying termination or change of control as described above under "— Potential Payments Upon Termination or Change of Control."

(4) Subject to an 18-month vesting schedule, vesting monthly in equal increments over the remaining 16-month period. The awards are also eligible for accelerated vesting on the closing of this offering, a qualifying termination or change of control as described above under "— Potential Payments Upon Termination or Change of Control."

(5) Subject to an 18-month vesting schedule, vesting monthly in equal increments over the remaining 17-month period. The awards are also eligible for accelerated vesting on the closing of this offering, a qualifying termination or change of control as described above under "— Potential Payments Upon Termination or Change of Control."

Employee Benefit and Stock Plans

Amended and Restated 2015 Equity Incentive Plan

Our board of directors initially adopted the 2015 Plan in April 2015, and our stockholders approved the 2015 Plan in April 2015. We intend to amend and restate the 2015 Plan in order to increase the share reserve under the 2015 Plan, include an "evergreen" provision, allow limited delegation of award authority to an executive officer and include certain annual limits on equity awards, which amendments will become effective immediately upon the execution and delivery of the underwriting agreement related to this offering. We refer to such amended and restated plan as the 2015 Plan.

Stock Awards. The 2015 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards (RSUs), performance-based stock awards, and other forms of equity compensation, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2015 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. When initially adopted, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2015 Plan was 1,000,000 shares. In addition, the maximum number of shares of our common stock that were issuable upon the exercise of ISOs under our 2015 Plan is 1,000,000 shares.

The aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2015 Plan after the amendment and restatement of our 2015 Plan becomes effective is shares. Additionally, the number of shares of our common stock reserved for issuance under our 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 (assuming the 2015 Plan becomes effective before such date) and continuing through and including January 1, 2025, by % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued upon the exercise of ISOs under our 2015 Plan is shares.

No person may be granted stock awards covering more than 1,000,000 shares of our common stock under our 2015 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 1,000,000 shares of our common stock or a performance cash award having a maximum value in excess of $1,000,000. Such limitations are designed to help ensure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code.

If a stock award granted under the 2015 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2015 Plan. In addition, the following types of shares of our common stock under the 2015 Plan may become available for the grant of new stock awards under the 2015 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2015 Plan may be previously unissued

shares or reacquired shares bought by us on the open market. As of the date hereof, no awards have been granted and no shares of our common stock have been issued under the 2015 Plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2015 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2015 Plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2015 Plan. Subject to the terms of our 2015 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2015 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2015 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2015 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2015 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2015 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2015 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) total stockholder return; (9) return on equity or average stockholder's equity; (10) return on assets, investment or capital employed; (11) stock price; (12) margin (including gross margin); (13) income (before or after taxes); (14) operating income; (15) operating income after taxes; (16) pre-tax profit; (17) operating cash flow; (18) sales or revenue targets; (19) increases in revenue or product revenue; (20) expenses and cost reduction goals; (21) improvement in or attainment of working capital levels; (22) economic value added (or an equivalent metric); (23) market share; (24) cash flow; (25) cash flow per share; (26) share price performance; (27) debt reduction; (28) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment, clinical trial results, new and supplemental indications for existing products, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals and product supply); (29) stockholders' equity; (30) capital expenditures; (31) debt levels; (32) operating profit or net operating profit; (33) workforce diversity; (34) growth of net income or operating income; (35) billings; (36) bookings; (37) employee retention; (38) initiation of phases of clinical trials and/or studies by specific dates; (39) patient enrollment rates; (40) budget management; (41) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a product candidate; (42) regulatory milestones; (43) progress of internal research or clinical programs; (44) progress of partnered programs; (45) partner satisfaction; (46) timely completion of clinical trials; (47) submission of INDs and new drug applications and other regulatory achievements; (48) research progress, including the development of programs; (49) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); and (50) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other

similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the performance goals and to define the manner of calculating the performance criteria we select to use for such performance period. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2015 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, (4) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2015 Plan pursuant to Section 162(m) of the Code) and (5) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2015 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional

acceleration of vesting and exercisability in the event of a change of control. For example, certain of our employees may receive an award agreement that provides for vesting acceleration upon the individual's termination without cause or resignation for good reason (including a material reduction in the individual's base salary, duties, responsibilities or authority, or a material relocation of the individual's principal place of employment with us) in connection with a change of control. Under the 2015 Plan, a change of control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (3) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets; or (4) the replacement of a majority of the directors who were on the board of directors at the time the 2015 Plan became effective, or the Incumbent Board, by directors who were not elected to the board by a majority of the directors who were sitting on the Incumbent Board.

Amendment and Termination. Our board of directors has the authority to amend, suspend, or terminate our 2015 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2015 Plan.

2015 Employee Stock Purchase Plan

We intend to adopt a 2015 Employee Stock Purchase Plan (ESPP), in order to enable eligible employees to purchase shares of our common stock at a discount following the date of this offering. The ESPP will become effective immediately upon the execution and delivery of the underwriting agreement related to this offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Share Reserve. Following this offering, the ESPP authorizes the issuance of shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2016 (assuming the ESPP becomes effective before such date) through January 1, 2025 by the least of (1) % of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and (2) shares. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to an amount determined by the board of directors, but not exceeding 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (1) 85% of the fair market value of a share of our common stock on the first date of an offering or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (1) customarily employed for more than

20 hours per week, (2) customarily employed for more than five months per calendar year or (3) continuous employment with us or one of our affiliates for a period of time, not to exceed two years. No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year and (3) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including the consummation of: (1) a sale of all our assets, (2) the sale or disposition of 90% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendments, Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Non-Employee Director Compensation

In the year ended December 31, 2014, we did not have any non-employee directors; therefore, we did not pay any fees to, make any equity awards or non-equity awards to, or pay any other compensation to non-employee members of our board of directors and none of our non-employee directors held any outstanding equity awards as of December 31, 2014. None of Ms. Sooch, our Chief Executive Officer, Dr. Bisgaier, the Chairman of our board of directors and our Chief Scientific Officer, or Mr. Lowenschuss, our Chief Legal Officer, received any compensation for his or her service as a director.

We intend to adopt a policy for compensating our non-employee directors with a combination of cash and equity that would become effective following the closing of this offering.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2012 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change of control and other arrangements, which are described under "Executive Officer and Director Compensation."

Merger with Michigan Life Therapeutics, LLC

In November 2014, pursuant to the Plan and Agreement of Merger with MLT, Dr. Bisgaier, our Chief Scientific Officer, chairman of our board of directors and co-founder, and Mr. Lowenschuss, our Chief Legal Officer, Secretary, director and co-founder, who were the only two members of MLT, received 3,720,000 and 2,480,000 shares of our common stock, respectively, of which 744,000 shares and 992,000 shares, respectively, are subject to vesting schedules pursuant to the employee agreements with such officers.

Lease with Michigan Life Ventures, LLC

On January 1, 2015, we entered into an office space sublease agreement with MLV. Pursuant to the lease, as amended, we currently lease an approximately 1,450 square foot facility in Northville, Michigan for a fixed rental fee of $2,250 per month, plus monthly cleaning fees. The current lease expires on September 30, 2015. Dr. Bisgaier, our Chief Scientific Officer and Chairman of our board of directors, and Mr. Lowenschuss, our Chief Legal Officer, Secretary and director, are members of MLV.

Pfizer Inc. License Agreement

In April 2011, we entered into the Pfizer Agreement for a worldwide exclusive license to certain patent rights to make, use, sell, offer for sale and import the clinical product candidate gemcabene. In exchange for this license, we agreed to issue shares of our common stock to Pfizer representing 15% of our fully diluted capital at the close of our first arms-length Series A financing.

We agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first regulatory submission in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene or any product containing gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

We have also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales as specified in the Pfizer Agreement until expiration of the last valid claim of the licensed patent rights, including any patent term extensions or supplemental protection certificates. Under the Pfizer Agreement we are obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

In March 2015, upon the closing of our Series A preferred stock financing, we issued 2,106,103 shares of our common stock to Pfizer in connection with the first equity payment, pursuant to which Pfizer became the owner of more than 5% of our capital stock.

The Pfizer Agreement will expire upon expiration of the last royalty term. Either party may terminate the Pfizer Agreement for the other party's uncured material breach and specified bankruptcy events. Pfizer may terminate the Pfizer Agreement if we or any of our sublicensees challenge the validity, enforceability or ownership of the licensed patents. Additionally, Pfizer may revoke the license if we are unable to adequately commercialize gemcabene by April 2021.

Promissory Notes, Convertible Note Financings and Preferred Stock

From March 2009 to October 2014, we borrowed an aggregate of $318,200 from, and issued promissory notes to, Dr. Bisgaier and Ms. McShane. These promissory notes were refinanced in connection with the convertible note financing discussed below.

On November 1, 2014, we entered into a convertible note financing pursuant to which we issued 8% convertible notes in an aggregate principal amount of $2.7 million to various investors from November 1, 2014 to February 18, 2015. On March 31, 2015, we also entered into a stock purchase agreement pursuant to which we agreed to issue and sell to various investors shares of our Series A convertible preferred stock at a per share price of $2.15. In connection with the stock purchase agreement, 125% of the unpaid principal plus any unpaid accrued interest on the notes was converted into shares of our Series A convertible preferred stock. Each share of Series A convertible preferred stock will convert into one share of our common stock upon the closing of this offering.

The following table summarizes the principal amount of convertible notes and shares of Series A convertible preferred stock purchased by members of our board of directors, executive officers or related parties.

Name of Noteholder	Principal Amount of Convertible Note ($)	Shares of Series A Convertible Preferred Stock Received Upon Conversion (#)	Value of Shares of Series A Convertible Preferred Stock Received Upon Conversion of Principal and Interest ($)	Additional Series A Convertible Preferred Stock Investment (#)	Additional Series A Convertible Preferred Stock Investment ($)
The Charles L. Bisgaier Trust Dated November 8, 2000[1]	311,517	185,770	399,406	—	—
The Margaret M. McShane Revocable Trust[2]	47,532	28,345	60,942	—	—
The Arvinder S. Sooch Trust Dated September 2006[3]	40,000	23,601	50,743	10,951	23,544
Edward Lowenschuss[4]	25,000	14,685	31,574	58,140	125,000
Michelle Johnson[5]	25,000	14,636	31,467	—	—
P. Kent Hawryluk Revocable Trust[6]	—	—	—	23,256	50,000
Andrew Sassine[7]	400,000	234,173	503,473	—	—
BWA Gemphire Investment Group, LLC[8]	—	—	—	297,674	640,000
Western Michigan University Research Foundation acting on behalf of Biosciences Research and Commercialization Center[9]	250,000	146,581	315,150	—	—

(1) Dr. Bisgaier, our Chief Scientific Officer and Chairman of our board of directors, is the trustee of The Charles L. Bisgaier Trust Dated November 8, 2000.

(2) Ms. McShane, our Vice President of Clinical and Project Management, is the trustee of The Margaret M. McShane Revocable Trust.

(3) The spouse of Ms. Sooch, our Chief Executive Officer and a member of our board of directors, is the trustee of The Arvinder S. Sooch Trust Dated September 2006.

(4) Edward Lowenschuss is the brother of Mr. Lowenschuss, our Chief Legal Officer and Secretary.

(5) Michelle Johnson is the sister-in-law of Dr. Bisgaier, our Chief Scientific Officer and Chairman of our board of directors.

(6) Mr. Hawryluk is a member of our board of directors.

(7) Mr. Sassine is a member of our board of directors.

(8) Kenneth Kousky, a member of our board of directors, is the manager of BWA Gemphire Investment Group, LLC.

(9) Stephen Haakenson, a former member of our board of directors, is an Executive Director of Biosciences Research & Commercialization Center.

On July 31, 2015, we entered into a convertible note financing in which we issued 8% convertible notes in an aggregate principal amount of $2.8 million to various investors. By their terms, upon any stock financing resulting in at least $5.0 million of new invested capital, 115% of the outstanding principal, plus accrued interest, under such notes shall convert into shares of the same series of stock issued in such financing at a conversion price equal to the per share price of the stock issued in such financing. In the event that we approve a change of control transaction or firmly underwritten public offering of our common stock prior to the consummation of such a stock financing, the convertible notes are repayable at the election of the holders of a majority of the outstanding principal amount, including a 100% premium on the principal amount if such repayment occurs in connection with a change of control transaction. In the event that a stock financing, change of control or initial public offering has not occurred by July 31, 2016, we are obligated to negotiate the conversion of the convertible notes into a new round of stock.

The following table summarizes the principal amount of convertible notes purchased by members of our board of directors, executive officers or related parties.

Name of Noteholder	Principal Amount of Convertible Note($)
The Charles L. Bisgaier Trust Dated November 8, 2000(1)	100,000
The Margaret M. McShane Revocable Trust(2)	20,000
The Arvinder S. Sooch Trust Dated September 2006(3)	25,000
Edward Lowenschuss(4)	150,000
Michelle Johnson(5)	25,000
P. Kent Hawryluk Revocable Trust(6)	50,000
Andrew Sassine(7)	100,000
BWA Gemphire Investment Group, LLC(8)	226,000
Western Michigan University Research Foundation acting on behalf of Biosciences Research and Commercialization Center(9)	100,000

(1) Dr. Bisgaier, our Chief Scientific Officer and Chairman of our board of directors, is the trustee of The Charles L. Bisgaier Trust Dated November 8, 2000.

(2) Ms. McShane, our Vice President of Clinical and Project Management, is the trustee of The Margaret M. McShane Revocable Trust.

(3) The spouse of Ms. Sooch, our Chief Executive Officer and a member of our board of directors, is the trustee of The Arvinder S. Sooch Trust Dated September 2006.

(4) Edward Lowenschuss is the brother of Mr. Lowenschuss, our Chief Legal Officer and Secretary.

(5) Michelle Johnson is the sister-in-law of Dr. Bisgaier, our Chief Scientific Officer and Chairman of our board of directors.

(6) Mr. Hawryluk is a member of our board of directors.

(7) Mr. Sassine is a member of our board of directors.

(8) Kenneth Kousky, a member of our board of directors, is the manager of BWA Gemphire Investment Group, LLC.

(9) Stephen Haakenson, a former member of our board of directors, is an Executive Director of Biosciences Research & Commercialization Center.

Investor Agreements

On November 1, 2014, we entered into a shareholders agreement with the Charles L. Bisgaier Trust dated November 8, 2000, as amended, of which Dr. Bisgaier is the Trustee, Mr. Lowenschuss, Ms. McShane, Dr. Oniciu and Ms. Sooch. The agreement contains rights of first offer, drag-along rights and tag-along rights. These rights will terminate upon the closing of this offering.

On November 1, 2014, we entered into a voting agreement with the Charles L. Bisgaier Trust dated November 8, 2000, as amended, of which Dr. Bisgaier is the Trustee, Mr. Lowenschuss, Ms. McShane, Dr. Oniciu and Ms. Sooch (collectively, the "Voting Agreement Shareholders"). The agreement obligates the Voting Agreement Shareholders to vote all of their shares of capital stock so as to elect three members of the Board as designated by the Voting Agreement Shareholders. These rights will terminate upon the closing of this offering.

In connection with our Series A convertible preferred stock financing, we entered into an investor rights agreement and right of first refusal and co-sale agreement containing voting rights, information rights, rights of first refusal and co-sale and registration rights, among other things, with each of the holders of our Series A convertible preferred stock. As detailed above, certain members of our board of directors, executive officers and related parties are holders of our Series A convertible preferred stock. These rights will terminate upon the closing of this offering, except for the registration rights as more fully described below in "Description of Capital Stock — Registration Rights."

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering. For more information regarding these indemnification arrangements, see "Management — Limitation on Liability and Indemnification of Directors and Officers." We believe that these provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Policies and Procedures for Transactions with Related Parties

The charter of our audit committee provides that it is the responsibility of our audit committee to review, approve and oversee any transaction between us and any related person and any other potential conflict of interest situations on an ongoing basis, in accordance with our policies and procedures, and to develop policies and procedures for the approval of related party transactions. Related party transactions also may be reviewed and approved at the full board level. Prior to consideration of a transaction with a related person, the material facts as to the related person's relationship or interest in the transaction are disclosed to our audit committee or the disinterested directors. The transaction is not approved unless a majority of the members of the committee or the full board who are not interested in the transaction approve the transaction. The audit committee takes into account, among other factors that it deems appropriate, whether the related person transaction is on terms no less favorable to us than terms generally available in a transaction with an unrelated third-party under the same or similar circumstances and the extent of the related person's interest in the related person transaction. Our current policy with respect to approval of related person transactions is not set forth in writing. We expect to adopt a written related person transaction policy to be effective upon the closing of this offering.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Beneficial ownership prior to this offering is based on 14,040,684 shares of common stock outstanding as of August 31, 2015, assuming the automatic conversion of all outstanding shares of our preferred stock into 2,325,581 shares of common stock.

Beneficial ownership after this offering is based on shares of common stock assumed to be outstanding after the closing of the offering, assuming (i) the automatic conversion of all outstanding shares of our preferred stock into common stock as described above, (ii) the issuance of shares of common stock pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy" immediately prior to the closing of the offering and (iii) the issuance of shares of common stock in this offering. We have assumed that no shares of our common stock are purchased by our directors or executive officers or by the beneficial owners of more than 5% of our capital stock pursuant to the directed share program or otherwise in the offering.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of August 31, 2015. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Gemphire Therapeutics Inc., 43334 Seven Mile Road, Suite 1000, Northville, Michigan 48167.

NAME AND ADDRESS OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
Greater than 5% stockholders			
Pfizer Inc.[1]	2,106,103	15.0%	
Directors and Named Executive Officers			
Mina Sooch[2]	2,050,832	14.6	
Charles L. Bisgaier, Ph.D.[3]	3,919,724	27.9	
David Lowenschuss[4]	2,487,256	17.7	
P. Kent Hawryluk[5]	123,256	*	
Kenneth Kousky[6]	306,007	2.2	
Andy Sassine[7]	250,840	1.8	
All current executive officers and directors as a group (9 persons)[8]	10,254,702	72.4%	

* Represents beneficial ownership of less than one percent.

(1) Represents 2,106,103 shares of common stock beneficially owned by Pfizer Inc. The address for Pfizer Inc. is 235 East 42nd St., New York, New York 10017.

(2) Represents (a) 2,000,000 shares of common stock held by Ms. Sooch, which become fully vested upon the closing of this offering, (b) 16,280 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2015 and (c) 34,552 shares of common stock issuable upon conversion of Series A convertible preferred stock held by Arvinder S. Sooch Trust Dated September 20, 2006, of which Ms. Sooch's spouse is the trustee.

(3) Represents (a) 3,720,000 shares of common stock held by Dr. Bisgaier, which become fully vested upon the closing of this offering, (b) 13,954 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2015 and (c) 185,770 shares of common stock issuable upon conversion of Series A convertible preferred stock held by The Charles L. Bisgaier Trust dated November 8, 2000, of which Dr. Bisgaier is the trustee.

(4) Represents (a) 2,480,000 shares of common stock held by Mr. Lowenschuss, which become fully vested upon the closing of this offering, and (b) 7,256 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2015.

(5) Represents (a) 100,000 shares of common stock held by P. Kent Hawryluk and (b) 23,256 shares of common stock issuable upon conversion of Series A convertible preferred stock held by the P. Kent Hawryluk Revocable Trust, of which Mr. Hawryluk is the trustee.

(6) Represents (a) 8,333 shares underlying options to purchase common stock exercisable within 60 days of August 31, 2015 and (b) 297,674 shares of common stock issuable upon conversion of Series A convertible preferred stock held by BWA Gemphire Investment Group, LLC. Mr. Kousky is the Manager of BWA Gemphire Investment Group, LLC. Mr. Kousky may be deemed to have voting and investment power over the shares owned by BWA Gemphire Investment Group, LLC.

(7) Represents (a) 16,667 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2015 and (b) 234,173 shares of common stock issuable upon conversion of Series A convertible preferred stock held by Mr. Sassine.

(8) Includes (a) the shares referenced in footnotes (2) - (7) above as well as (b) an additional 1,050,000 shares of common stock, which become fully vested upon the closing of this offering, 31,465 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2015 and 35,322 shares of common stock issuable upon conversion of Series A convertible preferred stock held by our executive officers.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights of our common and preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

General

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and shares of preferred stock, par value $0.001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated.

Common Stock

Outstanding Shares

As of August 31, 2015, there were 14,040,684 shares of common stock outstanding, held of record by 54 stockholders. Based on such number of shares of common stock outstanding as of August 31, 2015, and assuming (1) the conversion of all of our convertible preferred stock outstanding as of August 31, 2015 into 2,325,581 shares of common stock immediately prior to the closing of this offering, (2) the issuance of shares of common stock pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy" immediately prior to the closing of the offering and (3) the issuance by us of shares of common stock in this offering, there will be shares of common stock outstanding upon closing of this offering.

As of August 31, 2015, 585,122 shares of common stock were issuable upon the exercise of stock options outstanding as of August 31, 2015 at a weighted-average exercise price of $0.544 per share that were issued under our 2015 Plan. As of August 31, 2015, convertible bridge notes with an outstanding balance, including accrued interest, of $2.8 million were outstanding. Such notes may convert to shares of our capital stock as described under "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Historical Capital Resources."

Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a plurality of the shares of our common stock present at the meeting and entitled to vote in any election of directors can elect all of the directors standing for election. For most other matters, the approval of a majority of the shares voting at an annual or special meeting of stockholders will be required. Exceptions to this include removing directors for cause and amending certain sections of our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective upon the closing of this offering, each of which will require the approval of the holders of at least $66^{2}/_{3}\%$ of the voting power of all of our then outstanding common stock.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of

our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the 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.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Convertible Preferred Stock

As of August 31, 2015, we had outstanding an aggregate of 2,325,581 shares of Series A convertible preferred stock held of record by 40 stockholders.

Immediately prior to the closing of this offering, all outstanding shares of preferred stock at August 31, 2015 will convert into 2,325,581 shares of our common stock and we expect to issue shares of common stock pursuant to the Accrued Dividends described elsewhere in this prospectus in the section titled "Dividend Policy".

Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Stock Options

As of August 31, 2015, 585,122 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $0.544 per share.

Registration Rights

Following the closing of this offering, certain holders of our common stock, or their transferees, will be entitled to the registration rights set forth below with respect to registration of the resale of such shares under the Securities Act pursuant to the investors' rights agreement by and among us and certain of our stockholders.

Demand Registration Rights

At any time beginning six months after the public offering date set forth on the cover page of this prospectus, upon the written request of certain of the holders of the registrable securities then outstanding that we file a registration statement under the Securities Act covering the registration of the registrable securities having an aggregate offering price to the public of not less than $5 million, we will be obligated to notify all holders of registrable securities of such request and to use our reasonable best efforts to

register the sale of all registrable securities that holders may request to be registered. We are not required to effect more than two registration statements which are declared or ordered effective. We may postpone the filing or effectiveness of a registration statement for up to 90 days once in any twelve month period if our board of directors determines in its good faith judgment that such registration and offering would materially and adversely affect us. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

"Piggyback" Registration Rights

If we register any securities for public sale, holders of registration rights will have the right to include their shares in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters of any underwritten offering to limit the number of shares having registration rights to be included in the registration statement, but not below 30% of the total number of shares included in the registration statement, except this offering, in which the holders may be entirely excluded. Upon the closing of this offering, the holders of shares will be entitled to these piggyback registration rights.

Form S-3 Registration Rights

If we are eligible to file a registration statement on Form S-3, holders of at least 20% of the outstanding registrable securities will have the right to demand that we file a registration statement on Form S-3 so long as the aggregate price to the public of the securities to be sold under the registration statement on Form S-3 is at least $5 million. We are not required to effect more than two registrations on Form S-3 in any 12-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations. Upon such a request, we will be required to use our reasonable best efforts to file the registration as soon as practicable. Upon the closing of this offering, the holders of shares will be entitled to these Form S-3 registration rights.

Expenses of Registration

Generally, we are required to bear all registration and selling expenses incurred in connection with the demand, piggyback and Form S-3 registrations described above. All selling expenses incurred in connection with such registrations shall be borne by the holders of the securities so registered.

Expiration of Registration Rights

The demand, piggyback and Form S-3 registration rights discussed above will terminate as to a given holder of registrable securities upon the earlier of (i) five years following the closing of this offering or (ii) after the consummation of a liquidation event.

Anti-Takeover Provisions

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in 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 upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) 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

- on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^2/_3\%$ of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least $66^2/_3\%$ of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, which means that holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election;

- provide that special meetings of our stockholders may only be called by the chairman of the board of directors, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not any vacancies exist); and

- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, or (iv) any action asserting a claim against us governed by the internal affairs doctrine.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require the affirmative vote of the holders of at least $66^{2}/_{3}\%$ of the voting power of all of our then outstanding common stock.

NASDAQ Global Market Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent and registrar's address is and the telephone number is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the possibility of these sales occurring, could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of August 31, 2015, upon the closing of this offering, shares of common stock will be outstanding, or shares if the underwriters exercise the option to purchase additional shares in full. All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities who are subject to lock-up agreements described below and under "Underwriting" included elsewhere in this prospectus. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

- No restricted shares will be eligible for immediate sale upon the closing of this offering;
- Up to restricted shares will be eligible for sale under Rule 144 or Rule 701, subject to the volume limitations and manner of sale and notice provisions described below under "Rule 144," upon expiration of lock-up agreements at least 180 days after the date of this offering; and
- The remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective holding periods under Rule 144, but could be sold earlier if the holders exercise any available registration rights.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including any period of consecutive ownership of preceding non-affiliated holders, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including any period of consecutive ownership of preceding non-affiliated holders, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including any period of consecutive ownership of preceding non-affiliated holders, is entitled to sell a number of restricted shares within any three-month period 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 assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell unrestricted shares of our common stock must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Rule 701

Rule 701 under the Securities Act, as in effect on the effective date of the registration statement of which this prospectus is a part, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreements are entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effective date of the registration statement of which this prospectus is a part before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-Up Agreements

All of our directors and executive officers and the holders of all or substantially all our outstanding capital stock and other securities have signed a lock-up agreement in favor of the underwriters which prevents them from selling our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of 180 days from the date of the registration statement of which this prospectus is a part without the prior written consent of the representatives subject to certain exceptions set forth in "Underwriting". Jefferies LLC and Cowen and Company, LLC, on behalf of the underwriters, may in their discretion and at any time release some or all of the shares subject to lock-up agreements prior to the expiration of the 180-day period.

Registration Rights

Upon closing of this offering, the holders of shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described under "— Lock-Up Agreements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock — Registration Rights."

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the 2015 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

This section discusses the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock by a "Non-U.S. Holder". For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of common stock that, for U.S. federal income tax purposes, is neither a U.S. person nor an entity treated as a partnership. The term "U.S. person" means:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a court within the United States and which has one or more U.S. persons who have authority to control all substantive decisions of the trust, or (ii) which has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This discussion does not address entities that are, or are treated as, partnerships for U.S. federal income tax purposes (regardless of their place of organization or formation) and their equity holders, or entities that are disregarded for U.S. federal income tax purposes (regardless of their place of organization or formation). Therefore, these entities and persons are not considered "Non-U.S. Holders" for the purposes of this discussion.

This discussion generally does not address U.S. federal income tax considerations that may be relevant to particular investors because of their specific circumstances, or because they are subject to special rules. Investors subject to special rules not covered in this discussion include:

- financial institutions;
- insurance companies;
- tax-exempt organizations;
- tax-qualified retirement plans;
- broker-dealers and traders in securities, commodities or currencies;
- U.S. expatriates;
- "controlled foreign corporations;"
- "passive foreign investment companies;"
- corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock as part of a "straddle," "conversion transaction," or other risk reduction strategy, holders deemed to sell our common stock under the constructive sale provisions of the Code;
- holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation; and
- holders who are subject to the alternative minimum tax or the Medicare contribution tax.

Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders. This discussion does not provide a complete analysis of all potential tax considerations and does not address any federal gift or estate tax consequences (except to the limited extent set forth below), or state or local or non-U.S. tax consequences.

The discussion below is based upon the provisions of the Code and U.S. Treasury regulations, published administrative pronouncements, rulings and judicial decisions thereunder as of the date hereof. Such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following discussion. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice for any Non-U.S. Holders under their particular circumstances. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal tax consequences other than income or estate tax consequences.

Distributions on Our Common Stock

As described above in the "Dividend Policy" section of this prospectus, we do not anticipate paying any cash dividends in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions made to a Non-U.S. Holder generally will constitute dividends for U.S. tax purposes to the extent made out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those dividends exceed our current and accumulated earnings and profits, the dividends will constitute a return of capital and will first reduce a holder's basis, but not below zero, and then will be treated as gain from the sale of stock (described below).

The gross amount of any dividend (out of earnings and profits) paid to a Non-U.S. Holder generally will be subject to withholding tax at a 30% rate, unless the holder is entitled to an exemption from or reduced rate of withholding under an applicable income tax treaty. In order to receive an exemption or a reduced treaty rate, prior to the payment of a dividend, a Non-U.S. Holder must provide us with an IRS Form W-8BEN, Form W-8BEN-E, or other appropriate form, certifying the Non-U.S. Holder's qualification for the exemption or reduced rate.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates, unless a specific treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

A Non-U.S. Holder of common stock that is eligible for a reduced rate of withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts currently withheld, if an appropriate claim for refund is timely filed with the IRS.

Distributions on our common stock will also be subject to the discussion below regarding back-up withholding and foreign accounts.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock, unless:

- the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), in which case, the Non-U.S. Holder generally will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and if the Non-U.S. Holder is a corporation, an additional branch profits tax may apply, at a 30% rate or such lower rate as may be specified by an applicable income tax treaty;

- the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, in which case the Non-U.S. Holder will be required to pay a flat 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such Non-U.S. Holder's country of residence) on the net gain derived from the disposition, which tax may be offset by U.S. source capital losses (even though such Non-U.S. Holder is not considered a resident of the United States); or

- we are or have been a "U.S. real property holding corporation," or a USRPHC, within the meaning of Section 897(c)(2) of the Code at any time within the shorter of the five-year period preceding such disposition or such holder's holding period.

We believe that we are not, and do not anticipate becoming, a USRPHC.

Information Reporting Requirements and Backup Withholding

Generally, we must report annually to the IRS the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder. Pursuant to tax treaties or other agreements, the IRS may make its report available to tax authorities in the Non-U.S. Holder's country of residence.

A Non-U.S. Holder will be subject to backup withholding for dividends paid to such holder unless such holder certifies under penalty of perjury that it is a Non-U.S. Holder (and the payor does not have actual knowledge or reason to know that such holder is a U.S. person as defined under the Code), or such holder otherwise establishes an exemption.

Information reporting and, depending on the circumstances, backup withholding will apply to the proceeds of a sale of our common stock within the United States or conducted through certain U.S.-related financial intermediaries, unless the beneficial owner certifies under penalty of perjury that it is a Non-U.S. Holder (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person as defined under the Code), or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a credit or refund may be obtained from the IRS, so long as the required information is furnished to the IRS in a timely manner. If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax refund or credit with respect to the amount withheld.

Foreign Accounts

Sections 1471 through 1474 of the Code (such Sections commonly referred to as FATCA), generally may impose a U.S. federal withholding tax of 30% on dividends paid on our common stock and the gross

proceeds of a disposition of our common stock paid to non-U.S. financial institutions and certain non-U.S. non-financial entities (including, in some instances, where such an institution or entity is acting as an intermediary) unless they satisfy certain reporting requirements.

The withholding provisions described above generally apply to payments of dividends on our common stock and will apply to payments of gross proceeds from a sale or other disposition of our common stock on or after January 1, 2017.

Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Prospective investors are encouraged to consult with their own tax advisors regarding possible implications of FATCA on their investment in our common stock.

U.S. Federal Estate Tax

The estates of nonresident alien individuals are generally subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent. The U.S. federal estate tax liability of the estate of a nonresident alien may be affected by a tax treaty between the United States and the decedent's country of residence.

THE PRECEDING DISCUSSION OF MATERIAL U.S. FEDERAL TAX CONSEQUENCES IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE FOR ANY NON-U.S. HOLDERS UNDER THEIR PARTICULAR CIRCUMSTANCES. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF ACQUIRING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL TAX LAWS OTHER THAN INCOME TAXES.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2015, among us and Jefferies LLC and Cowen and Company, LLC, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
Cowen and Company, LLC	
Roth Capital Markets, LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

At our request, the underwriters have reserved up to % of the shares of our common stock offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees and other individuals associated with us and members of their respective families. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. The underwriters will receive the same underwriting discount on any shares purchased by these investors as they will on any other shares sold to the public in this offering. Any shares purchased by such investors will be subject to the lock-up restrictions described herein.

The underwriters have advised us that, following the closing of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common

stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

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 also agreed to reimburse the underwriters for up to $ for their FINRA counsel fee. In accordance with FINRA 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We intend to apply to have our common stock approved for listing on the NASDAQ Global Market under the symbol "GEMP."

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended,
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially,
- enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of shares of our common stock, or of options or warrants to shares of our common stock, or securities or rights exchangeable or exercisable for or convertible into shares of our common stock,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any shares of our common stock, or of options or warrants to shares of our common stock, or securities or rights exchangeable or exercisable for or convertible into shares of our common stock, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Cowen and Company, LLC.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus. In addition, the foregoing shall not apply to issuances of common stock or grants of stock options, restricted stock or other incentive compensation pursuant to the terms of certain stock plans or arrangements described herein.

Jefferies LLC and Cowen and Company, LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales 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 may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the NASDAQ Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of 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 certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Canada

The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 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 underwriters or the underwriters nominated by us for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require us or any of the underwriters to publish 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, the expression an "offer of securities to the public" in relation to any securities 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 the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and 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 the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong)

other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated, each such person being referred to as a relevant person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered hereby and certain legal matters in connection with this offering will be passed upon for us by Honigman Miller Schwartz and Cohn LLP, Kalamazoo, Michigan. Cooley LLP, New York, New York, is counsel for the underwriters in connection with this offering.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2013 and 2014 and for the years then ended, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to the financial statements). We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 43334 Seven Mile Road, Suite 1000, Northville, Michigan 48167, or telephoning us at (248) 681-9815.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934 and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.gemphire.com, at which, following the closing 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 or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Index to The Financial Statements

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Financial Statements
For the years ended December 31, 2013 and 2014
and for the six months ended June 30, 2014 and 2015

Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Gemphire Therapeutics Inc.

We have audited the accompanying balance sheets of Gemphire Therapeutics Inc. (formerly known as Michigan Life Therapeutics, LLC) (the Company) as of December 31, 2013 and 2014, and the related statements of comprehensive loss, changes in convertible preferred stock and stockholders' and members' deficit and cash flows for each of the two years in the period ended December 31, 2014. 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). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's 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, and 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 Gemphire Therapeutics Inc. (formerly known as Michigan Life Therapeutics, LLC) at December 31, 2013 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 of the financial statements, the Company has recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP
Detroit, Michigan
September 10, 2015

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Balance Sheets

	December 31, 2013	December 31, 2014	June 30, 2015 (unaudited)	Pro forma June 30, 2015 (unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 3,300	$ 317,172	$ 2,189,270	$
Prepaid expenses	14,244	12,670	12,328	
Total current assets	17,544	329,842	2,201,598	
Deferred tax assets	—	17,717	19,881	
Total assets	$ 17,544	$ 347,559	$ 2,221,479	$
Liabilities, convertible preferred stock and shareholders' and members' deficit				
Current liabilities:				
Accounts payable	$ 26,375	$ 20,596	$ 426,344	$
Accrued liabilities	9,233	30,169	216,186	
Deferred tax liabilities	—	17,717	19,881	
Convertible notes to related parties	—	377,176	—	
Convertible notes	—	359,768	—	
Premium conversion derivative	—	72,621	—	
Total current liabilities	35,608	878,047	662,411	
Long-term promissory notes	245,858	—	—	
Total liabilities	281,466	878,047	662,411	
Commitments and contingencies (Note 5)				
Series A convertible preferred stock, $0.001 par value; no shares authorized as of December 31, 2013 and 2014, and 2,325,581 shares authorized as of June 30, 2015 (unaudited), respectively; no shares issued as of December 31, 2013 and 2014, and 2,325,581 shares issued as of June 30, 2015, respectively; no aggregate liquidation preference as of December 31, 2013 and 2014, and aggregate liquidation preference of $7,651,231 as of June 30, 2015 (unaudited), respectively	—	—	7,651,231	
Members' deficit	(263,922)	—	—	
Stockholders' deficit:				
Common stock par value $0.001; no shares authorized as of December 31, 2013, 20,000,000 shares authorized as of December 31, 2014 and 17,674,419 shares authorized as of June 30, 2015 (unaudited), respectively, no shares outstanding at December 31, 2013, 9,470,000 and 11,715,103 shares issued and outstanding at December 31, 2014 and June 30, 2015 (unaudited), respectively	—	9,470	11,715	
Additional paid-in capital	—	44,176	—	
Accumulated deficit	—	(584,134)	(6,103,878)	
Total stockholders' deficit	—	(530,488)	(6,092,163)	
Total liabilities, convertible preferred stock and stockholders' and members' deficit	$ 17,544	$ 347,559	$ 2,221,479	$

See accompanying notes.

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Statements of Comprehensive Loss

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
			(unaudited)	
Operating expenses:				
General and administrative	$ 96,727	$ 214,228	$ 47,641	$ 1,133,387
Research and development	1,418	52,100	42,517	1,158,589
Acquired in-process research and development	—	—	—	907,730
Total operating expenses	98,145	266,328	90,158	3,199,706
Loss from operations	(98,145)	(266,328)	(90,158)	(3,199,706)
Interest expense	(13,096)	(54,507)	(10,323)	(690,016)
Other income (expense), net	1	623	—	(564)
Net loss	(111,240)	(320,212)	(100,481)	(3,890,286)
Other comprehensive loss, net of tax	—	—	—	—
Comprehensive loss	$ (111,240)	$ (320,212)	$ (100,481)	$ (3,890,286)
Net loss per share:				
Basic and diluted (Note 10)		$ (0.07)		$ (0.83)
Number of shares used in per share calculations:				
Basic and diluted		4,746,648		7,902,438
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) (Note 2)		$		$
Weighted-average shares used in computing pro forma net loss attributable to common stockholders, basic and diluted (unaudited) (Note 2)				

See accompanying notes.

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Statements of Changes in Convertible Preferred Stock and Stockholders' and Members' Deficit
(period from January 1, 2015 through June 30, 2015 is unaudited)

	Series A Convertible Preferred Stock			Common Stock				
	Shares	Amount	Members' Deficit	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Deficit
Balance at January 1, 2013	—	$ —	$ (152,682)	—	$ —	$ —	$ —	$ (152,682)
Net loss	—	—	(111,240)	—	—		—	(111,240)
Balance at December 31, 2013	—	—	(263,922)	—	—	—	—	(263,922)
Net loss prior to merger	—	—	(124,382)	—	—	—	—	(124,382)
Effect of merger	—	—	388,304	6,200,000	6,200	(6,200)	(388,304)	—
Restriction of initial common stock issuances	—	—	—	(1,736,000)	(1,736)	1,736	—	—
Issuance of restricted stock awards	—	—	—	5,006,000	5,006	(5,006)	—	—
Share-based compensation — employee	—	—	—	—	—	53,284	—	53,284
Share-based compensation — non-employee	—	—	—	—	—	362	—	362
Net loss post merger	—	—	—	—	—	—	(195,830)	(195,830)
Balance at December 31, 2014	—	—	—	9,470,000	9,470	44,176	(584,134)	(530,488)
Issuance of convertible Series A preferred stock, net of issuance costs	2,325,581	4,984,999	—	—	—	—	—	—
Redemption value adjustment — Series A preferred stock	—	2,666,232	—	—	—	(1,036,774)	(1,629,458)	(2,666,232)
Issuance of common stock	—	—	—	2,106,103	2,106	905,624	—	907,730
Issuance of restricted stock awards	—	—	—	139,000	139	(139)	—	—
Share-based compensation — employee	—	—	—	—	—	43,451	—	43,451
Share-based compensation — non-employee	—	—	—	—	—	43,662	—	43,662
Net loss	—	—	—	—	—	—	(3,890,286)	(3,890,286)
Balance at June 30, 2015	2,325,581	$ 7,651,231	$ —	11,715,103	$ 11,715	$ —	$ (6,103,878)	$ (6,092,163)

See accompanying notes.

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Statements of Cash Flows

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
			(unaudited)	
Operating activities				
Net loss	$ (111,240)	$ (320,212)	$ (100,481)	$ (3,890,286)
Adjustments to reconcile net loss to net cash used in operating activities:				
Share-based compensation	—	53,646	—	87,113
Non-cash interest on promissory notes to related parties	13,096	18,991	10,323	—
Non-cash interest on convertible notes to related parties	—	4,909	—	11,179
Non-cash interest on convertible notes	—	1,198	—	21,925
Non-cash discount amortization on convertible notes to related parties	—	6,825	—	48,879
Non-cash discount amortization on convertible notes	—	4,889	—	226,644
Revaluation of premium conversion derivative	—	17,695	—	379,830
Non-cash acquisition of in-process research and development	—	—	—	907,730
Change in assets and liabilities:				
Prepaid expenses	560	1,574	8,244	342
Accounts payable	6,540	(5,779)	6,770	405,748
Accrued liabilities	(17,598)	20,936	34,891	186,017
Net cash used in operating activities	(108,642)	(195,328)	(40,253)	(1,614,879)
Investing activities				
Net cash provided by (used in) investing activities	—	—	—	—
Financing activities				
Proceeds from issuance of convertible notes	—	390,000	—	1,650,000
Proceeds from issuance of convertible notes to related parties	—	25,000	—	315,000
Proceeds from issuance of promissory notes to related parties	108,000	94,200	45,000	—
Proceeds from issuance of Series A convertible preferred stock	—	—	—	1,521,977
Net cash provided by financing activities	108,000	509,200	45,000	3,486,977
Net (decrease) increase in cash and cash equivalents	(642)	313,872	4,747	1,872,098
Cash and cash equivalents at beginning of period	3,942	3,300	3,300	317,172
Cash and cash equivalents at end of period	$ 3,300	$ 317,172	$ 8,047	$ 2,189,270
Supplemental disclosure of cash flow information:				
Cash paid for interest	$ —	$ —	$ —	$ 1,559
Supplemental non-cash financing transactions:				
Conversion of convertible notes to Series A preferred stock	$ —	$ —	$ —	$ 2,778,261
Exercise of premium conversion derivative	$ —	$ —	$ —	$ 684,761
Redemption value change of Series A preferred stock	$ —	$ —	$ —	$ 2,666,232
Issuance of common stock for acquisition of in-process research and development	$ —	$ —	$ —	$ 907,730
Bifurcation of premium conversion derivative related to convertible notes	$ —	$ 54,926	$ —	$ 232,310
Conversion of related party promissory notes to convertible notes	$ —	$ 359,049	$ —	$ —

See accompanying notes.

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Notes to Financial Statements
(Information as of June 30, 2015 and thereafter and for the six months ended June 30, 2014 and 2015 is unaudited)

1. The Company and Basis of Presentation

On November 10, 2008, Michigan Life Therapeutics, LLC (MLT) was organized as a limited liability company (LLC) in Michigan. On October 30, 2014, Gemphire Therapeutics Inc. (Gemphire) was incorporated as a C corporation in the state of Delaware. On November 1, 2014, MLT entered into a merger agreement with Gemphire whereby MLT was merged with and into Gemphire with Gemphire as the surviving entity; all outstanding membership interests of MLT were exchanged for shares of Gemphire's common stock. The purpose of the merger was to change the jurisdiction of MLT from Michigan to Delaware and to convert from an LLC to a corporation. All financial results presented prior to November 1, 2014 are from the operations of MLT. MLT and Gemphire are collectively referred to as the "Company" in the accompanying notes to the financial statements. The Company's headquarters is located in Northville, Michigan.

We are a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease. The Company's primary activities have been conducting research and development activities, planning clinical trials, performing business and financial planning, recruiting personnel and raising capital. The Company is subject to certain risks, which include the need to research, develop, and clinically test potentially therapeutic products, initially one product candidate gemcabene (also known as CI-1027); obtain regulatory approval for its products and commercialize them around the world; expand its management scientific staff; finance its operations; and, find collaboration partners to further advance development and commercial efforts.

The Company has sustained operating losses since inception and expects such losses to continue over the next several years. Management plans to continue financing the operations with equity issuances. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate part or all of its research and development programs.

Going Concern

The Company's ability to continue operating as a going concern is contingent upon, among other things, its ability to secure additional financing and to achieve and maintain profitable operations. The Company plans to issue additional convertible debt and equity instruments to finance operating and working capital requirements. While the Company expects to obtain the additional financing that is needed, there is no assurance that the Company will be successful in obtaining the necessary funding for future operations. These factors raise substantial doubt as to the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Unaudited Interim Financial Statements

The accompanying financial statements and the financial data disclosed in the notes to the financial statements for the six months ended June 30, 2014 and 2015 have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC).

The unaudited interim financial statements have been prepared on the same basis as the annual financial statements, and in the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Notes to Financial Statements — (Continued)
(Information as of June 30, 2015 and thereafter and for the six months ended June 30, 2014 and 2015 is unaudited)

for the interim periods, have been made. The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of deposit to be cash equivalents.

Fair Value of Financial Instruments

The Company's financial instruments include principally cash and cash equivalents, other current assets, accounts payable, accrued liabilities and debt. The carrying amounts for these financial instruments reported in the balance sheets approximate their fair values. See Note 11 — Fair Value Measurements, for further discussion of fair value.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries and share-based compensation costs, for personnel in functions not directly associated with research and development activities. Other significant costs include legal fees related to intellectual property and corporate matters and professional fees for accounting and other services.

Research and Development Expenses

Research and development expenses consist of costs incurred in performing research and development activities, including compensation for research and development employees, costs associated with preclinical studies and trials, regulatory activities, manufacturing activities to support clinical activities, license fees, nonlegal patent costs, fees paid to external service providers that conduct certain research and development, clinical costs and an allocation of overhead expenses. Research and development costs are expensed as incurred.

Acquired In-Process Research and Development Expenses

The Company includes costs to acquire or in-license product candidates in acquired in-process research and development expenses. The Company has acquired the right to develop and commercialize its product candidate gemcabene. These costs are immediately expensed provided that the payments do not also represent processes or activities that would constitute a "business" as defined under GAAP or provided that the product candidate has not achieved regulatory approval for marketing and, and absent obtaining such approval, has no alternative future use. Royalties owed on future sales of any licensed product will be expensed in the period the related revenues are recognized.

Gemphire Therapeutics Inc.
(Formerly Known as Michigan Life Therapeutics, LLC)
Notes to Financial Statements — (Continued)
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Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by Accounting Standards Codification (ASC) 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. Currently, there is no provision for income taxes, as the Company has incurred operating losses to date, and a full valuation allowance has been provided on the net deferred tax assets. MLT was treated as a partnership for federal and state income tax purposes. Accordingly, no provision was made for income taxes for periods prior to November 1, 2014, since the Company's net loss (subject to certain limitations) was passed through to the income tax returns of its members. Upon incorporation on October 30, 2014, the Company became taxed as a corporation.

Share-Based Compensation

The Company accounts for share-based compensation in accordance with the provisions of ASC 718, *Compensation — Stock Compensation* (ASC 718). Accordingly, compensation costs related to equity instruments granted are recognized at the grant-date fair value. Additionally, under the provisions of ASC 718, the Company is required to include an estimate of the number of awards that will be forfeited in calculating compensation costs, which are recognized over the requisite service period of the awards (typically the vesting period of the awards). Share-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718 and ASC 505, *Equity*, using a fair value approach. The compensation costs of these arrangements are subject to re-measurement as the equity instruments vest and are recognized as expense over the related service period (typically the vesting period of the awards).

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. The valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions affecting the biopharmaceutical industry sector, and the likelihood of achieving a liquidity event, such as an initial public offering (IPO) or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Convertible Preferred Stock

On March 31, 2015, the Company issued 2,325,581 shares of Series A convertible preferred stock (the Series A preferred stock). The Series A preferred stock is classified outside of permanent equity, in mezzanine equity, on the Company's June 30, 2015 balance sheet. The Company initially records preferred stock that may be redeemed at the option of the holder, or based on the occurrence of events outside of the Company's control, at the value of the proceeds received. Subsequently, if it is probable that the preferred stock will become redeemable, the Company recognizes changes in the redemption value immediately as they occur and adjusts the carrying amount of the instrument to equal the redemption value at the end of each reporting period. If it is not probable that the preferred stock will become redeemable, the Company

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does not adjust the carrying value. In the absence of retained earnings, these charges are recorded against additional paid-in-capital, if any, and then to accumulated deficit. See Note 7 — *Convertible Series A Preferred Stock* for further discussion.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development and commercialization of therapeutics to treat cardiovascular and metabolic diseases. Accordingly, the Company has a single reporting segment.

Jumpstart Our Business Startups Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act), the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company has irrevocably elected not to avail ourselves of this exemption and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Unaudited Pro Forma Balance Sheet and Net Loss Per Common Share

The unaudited pro forma balance sheet as of June 30, 2015 reflects: (1) the automatic conversion of all outstanding shares of the Company's Series A preferred stock into an aggregate of 2,325,581 shares of common stock immediately prior to the completion of an IPO; (2) the issuance of shares of common stock in accrued dividends to our existing holders of the Series A preferred stock upon the conversion of their Series A preferred stock into common stock in connection with an IPO, as described in Note 5 below, immediately prior to the closing of an IPO; and (3) the immediate vesting of 2,008,097 shares of restricted stock, valued at $56,227, held by certain employees upon the closing of an IPO. The pro forma basic and diluted net loss per share attributable to common stockholders does not include shares expected to be sold and related proceeds to be received from an IPO.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-11, *Income Taxes — Topic 740*, which is an amendment to the accounting guidance on income taxes. This guidance provides clarification on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The amendment was effective for the Company for interim and annual periods beginning after December 15, 2013, with early adoption permitted. The adoption of this standard did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers — Topic 606*, which supersedes the revenue recognition requirements in FASB ASC 605. The new guidance primarily states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In 2015, the FASB agreed to allow companies to delay the

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implementation of this standard for one year effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is permitted only for periods beginning after December 15, 2016. The Company is evaluating its implementation method and the impact of adopting this prospective guidance on its financial statements.

In June 2014, the FASB issued ASU 2014-10, *Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. This guidance removed all incremental financial reporting requirements from GAAP for development stage entities, thereby improving financial reporting by eliminating the cost and complexity associated with providing that information. The effective date of the amendment is staggered for public and nonpublic entities with the first date being for annual periods beginning after December 15, 2014, with early adoption permitted for financial statements that have not yet been issued or available to be issued. The Company elected to adopt this standard early to take effect in the accompanying financial statements and related footnotes.

In June 2014, the FASB issued ASU 2014-12, *Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* (ASU 2014-12). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in ASC 718, as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (1) prospectively to all awards granted or modified after the effective date; or (2) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In August 2014, the FASB issued Accounting Standards Update 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), which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events that, considered in the aggregate, raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued, when applicable) and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company elected to adopt this standard early to take effect in the accompanying financial statements and related footnotes.

In January 2015, the FASB issued ASU 2015-01, *Income Statement — Extraordinary and Unusual Items* (ASU 2015-01). ASU 2015-01 eliminates from GAAP the concept of extraordinary items. As a result, an entity will no longer be required to separately present an extraordinary item on its statement of comprehensive loss, net of tax, after income from continuing operations, or disclose income taxes and net income per share data applicable to an extraordinary item. However, ASU 2015-01 will still retain the presentation and disclosure guidance for items that are unusual in nature and occur infrequently. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after

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December 15, 2015. Early adoption is permitted provided the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect the adoption of this standard to have a material impact on its financial statements, absent any material transactions in future periods that would qualify for extraordinary item presentation under the prior guidance.

In April 2015, the FASB issued ASU 2015-03, *Interest — Imputation of Interest* (ASU 2015-03). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. For public entities, ASU 2015-03 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

3. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,		
	2013	2014	June 30, 2015 (unaudited)
Legal fees	$ 8,602	$ 24,645	$ 92,000
Payroll	—	—	32,794
Other professional fees	—	—	50,892
Other	631	5,524	40,500
Total	$ 9,233	$ 30,169	$ 216,186

4. Debt

Promissory Notes to Related Parties

The Company issued promissory notes to related parties (the Promissory Notes) at a compound interest rate of 8% per annum for an aggregate principal amount of $318,200 on various dates from March 2009 through October 2014 with maturity dates through October 31, 2014. The Promissory Notes consisted of the following:

	December 31,	
	2013	2014
Note A	$ 225,659	$ —
Note B	20,199	—
Total	$ 245,858	$ —

The Promissory Notes along with accrued interest were exchanged for convertible notes (the Convertible Notes) on November 1, 2014, in the amount of $359,049 inclusive of accrued interest, which were included in a series of financings with certain investors, beginning on November 1, 2014 and ending on February 18, 2015, whereby a total of $2,739,049 was loaned to the Company, of which $1,965,000 was loaned in 2015. Interest for the Convertible Notes compounded on a daily basis at a rate of 8 percent per annum. The Convertible Notes were converted into shares of the Company's Series A preferred stock upon close of the preferred stock financing (the Preferred Financing) on March 31, 2015. The conversion equaled 125% of the unpaid principal plus unpaid accrued interest on the Convertible Notes.

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The holders of the Convertible Notes received the benefit of a premium at the time of their issuance with regard to the conversion into the Series A preferred stock. The Company determined that this redemption feature qualified as an embedded derivative and was separated from its debt host. The embedded derivative was accounted for separately on a fair market value basis up to the point of the close of the Preferred Financing. The fair value of this derivative was $72,621 at December 31, 2014, which amount was included as a premium conversion derivative on the accompanying balance sheet. The Company recorded the fair value changes of the premium conversion derivative to interest expense that amounted to $17,695 and $379,830 for the year ended December 31, 2014 and the six months ended June 30, 2015, respectively. Lastly, the bifurcation of the embedded derivative from the debt host resulted in a discount to the Convertible Notes. The discount was being amortized to interest expense over the term of the Convertible Notes using the straight-line method until their conversion on March 31, 2015.

5. Commitments and Contingencies

Pfizer License Agreement

In April 2011, the Company and Pfizer Inc. (Pfizer) entered into an exclusive license agreement (the Pfizer Agreement) for the clinical product candidate gemcabene. In exchange for this worldwide exclusive right and license to certain patent rights to make, use, sell, offer for sale and import the clinical product gemcabene, the Company agreed to certain milestone and royalty payments on future sales (See Note 6 — *License Agreement)*. As of June 30, 2015, there was sufficient uncertainty with regard to both the outcome of the clinical trials and the ability to obtain sufficient funding to support any of the cash milestone payments under the license agreement, and as such, no liabilities were recorded related to the license agreement.

Series A Preferred Stock Dividends

Holders of the Series A preferred stock are entitled to cumulative accruing dividends at a simple rate of 8% per year on the original issue price of the preferred stock of $2.15 per share. The dividends effectively accrue daily on each share of preferred stock. The dividends are payable upon the earliest to occur of (1) the date determined by the Board, (2) the liquidation of the Company (including a deemed liquidation event) or (3) the conversion or redemption of at least a majority of the outstanding shares of Series A preferred stock. If the board reasonably believes that the Company is not legally able to pay the dividends in cash at the payment date, or if elected by the majority of the Series A preferred stockholders or if issued in connection with an IPO, the dividends shall be paid in shares of common stock at the conversion price for the Series A preferred stock in effect at that time, which is the original issue price of the Series A preferred stock as adjusted from time to time for any stock dividends, combinations, splits or recapitalizations. Since the dividends are payable upon a contingent event, the Company has not recorded them in the accompanying financial statements. Cumulative unpaid dividends for the Series A preferred stock totaled zero as of the years ended December 31, 2013 and 2014 and $100,822 at June 30, 2015.

Other Agreements

A non-cancellable facility agreement was in place that provided for fixed monthly rent for the years ended December 31, 2013 and 2014 and the six months ended June 30, 2014 and 2015. The total rent expense for the years ended December 31, 2013 and 2014 was $6,000 in each period, and total rent expense for the six months ended June 30, 2014 and 2015 was $3,000 and 9,260, respectively.

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6. License Agreement

In April 2011, the Company entered into the Pfizer Agreement for a worldwide exclusive license to certain patent rights to make, use, sell, offer for sale and import the clinical product candidate gemcabene. In exchange for this license, the Company agreed to issue shares of its common stock to Pfizer representing 15% of the Company's fully diluted capital at the close of the its first arms-length Series A financing, which occurred on March 31, 2015.

We agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first regulatory submission in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene or any product containing gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

The Company also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales, as specified in the Pfizer Agreement until expiration of the last valid claim of the licensed patent rights including any patent term extensions or supplemental protection certificates. Under the Pfizer Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

On March 31, 2015, upon the closing of the Series A preferred stock financing, the Company issued 2,106,103 shares of its common stock, at a fair market value of $907,730, to Pfizer in connection with the first equity payment, pursuant to which Pfizer became the owner of more than 5% of the Company's capital stock. The transaction was recorded as acquired in-process research and development expenses based on the fair market value of the common shares issued since no processes or activities that would constitute a "business" were acquired and none of the rights and underlying assets acquired had alternative future uses or reached a stage of technological feasibility. None of the other milestone or royalty payments were triggered as of June 30, 2015

The Pfizer Agreement will expire upon expiration of the last royalty term. Either party may terminate the Pfizer Agreement for the other party's uncured material breach or upon specified bankruptcy events. Pfizer may terminate the Pfizer Agreement if the Company or any of its sublicensees challenge the validity, enforceability or ownership of the licensed patents. Additionally, Pfizer may revoke the license if the Company is unable to adequately commercialize gemcabene by April 2021.

7. Convertible Series A Preferred Stock

On March 31, 2015, the Company issued 2,325,581 shares of Series A preferred stock at a per share price of $2.15, or $5.0 million in the aggregate, consisting of $1.5 million in cash and $3.5 million representing 125% of the principal and accrued and unpaid interest on the Convertible Notes, all of which converted into shares of Series A preferred stock.

The Series A preferred stock has the following rights and preferences:

Dividend Rights

Dividends effectively accrue on a daily basis at a simple rate of 8% per annum on the sum of the original per share issue price. Dividends are effectively deemed declared daily and are payable upon the occurrence of certain events. In addition, the holders of the Series A preferred stock have rights to participate in

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common stock dividends, entitling holders of Series A preferred stock to a dividend payable at the same time as the dividend paid on common stock based on the number of shares of common stock each share of Series A preferred stock would convert into if such shares had converted on the record date. There were no dividends deemed payable and accrued, but unpaid dividends were zero as of December 31, 2013 and 2014 and $100,822 as of June 30, 2015. (See Note 5 — *Commitments and Contingencies*).

Voting Rights

Each share of Series A preferred stock shall be entitled to vote together with the common stock on all actions to be taken by the stockholders of the Company, based on the number of shares of common stock into which each share of Series A preferred stock could be converted. A separate vote of a majority of the outstanding shares of Series A preferred stock is required to (1) issue or authorize any class or series of equity securities or equivalents, (2) effect any transaction that results in a change in control, (3) change the principal business of the Company, enter new lines of business, or exit the current line of business, (4) issue of convertible debt above a certain threshold, or (5) materially sell, transfer, license, pledge or encumber technology or intellectual property. A management stock option plan approved by the board of directors, however, is not subject to a separate vote of the Series A preferred stockholders, but any subsequent increases to the authorized option pool are subject to approval by the Series A preferred stock holders via a separate vote.

Liquidation Rights

In the event of any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary, merger, consolidation or transaction in which over 50% of the Company's voting power is transferred, or a sale, lease, transfer, exclusive license or disposition of all or substantially all of the assets of the Company, the Series A preferred stock holders shall be entitled to the assets of the Company legally available for distribution before any distribution or payment is made to the holders of common stock. The distribution amount shall equal the original issue price of the Series A preferred stock (as adjusted for any stock dividends, combinations, splits or other recapitalizations since issuance), plus any accrued or declared but unpaid dividends thereon. After payment of the full liquidation preference to the Series A preferred stock holders, the remaining assets legally available for distribution shall be distributed to the holders of common stock and holders of the Series A preferred stock pro rata based on the number of shares of common stock each share of Series A preferred stock would convert into if such shares had converted immediately prior to such liquidation, dissolution, or winding-up.

Conversion Rights

Shares of Series A preferred stock, at the option of the holder, may be converted at any time into shares of common stock. The conversion rate shall be obtained by dividing the Series A preferred stock original issue price of $2.15 per share by the conversion price per share in effect at the time of conversion. The Series A conversion price is initially equal to the original issue price, but shall be adjusted on a broad-based weighted average basis in connection with certain dilutive events. The conversion price for the Series A preferred stock was $2.15 per share at June 30, 2015. The Series A holder would also be entitled to receive additional shares of common stock for any unpaid Series A dividends (whether or not declared).

Shares of Series A preferred stock shall automatically be converted into common stock based upon the then-effective Series A conversion price upon the affirmative vote or consent of the holders of at least a majority of the outstanding shares of the Series A preferred stock, or at the closing of a firmly underwritten public offering whereby the common stock of the Company is listed on a U.S. national securities exchange

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and with a public offering price of at least 1.5 times the Series A original issue price of $2.15 and net cash proceeds before underwriting discounts of at least $50 million.

Redemption Rights

The holders of at least 80% of the outstanding shares of Series A preferred stock may require the Company to redeem all outstanding shares of Series A preferred stock at any time on or after December 31, 2020 at a redemption price equal to the greater of 150% of the liquidation preference of the Series A preferred stock or the fair market value per share plus any unpaid declared dividends. The liquidation preference of the Series A preferred stock is defined as an amount per share equal to $2.15, as adjusted from time to time for any stock dividends, combinations, splits or recapitalizations, plus any accrued or declared but unpaid dividends thereon.

The redemption value for redeemable preferred stock may at times be based on fair market value. The assumptions used in calculating the estimated fair market value at each reporting period represent the Company's best estimate, however, inherent uncertainties are involved. As a result, if factors or assumptions change, the estimated fair value could be materially different. As of June 30, 2015, the estimated fair value of the Series A preferred stock was $5.1 million.

The Company recognizes changes in the redemption value immediately as they occur and adjusts the carrying amount of the instrument to equal the redemption value at the end of each reporting period since it is probable that the instruments will become redeemable. In the absence of retained earnings, these charges are recorded against additional paid-in-capital, if any, and then to accumulated deficit.

The Company evaluated the Series A preferred stock and determined that it is considered an equity host under ASC 815**,** *Derivatives and Hedging.* In making this determination, the Company's analysis followed the whole instrument approach that compared an individual feature against the entire Series A preferred stock instrument that included that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of the Series A preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features of the Series A preferred stock, including: (1) redemption features and their underlying exercisability, (2) existence of any protective covenants, (3) nature of dividends rights, (4) nature of voting rights, and (5) the existence and nature of any conversion rights. As a result of the above, the Company concluded that the Series A preferred stock represented an equity host, and as such, the redemption and/or conversion features of the Series A preferred stock were considered to be clearly and closely related to the associated Series A preferred stock host instrument. Accordingly, the redemption and/or conversion features of the Series A preferred stock were not considered an embedded derivative that required bifurcation.

8. Stockholders' and Members' Deficit

The membership interests of MLT were converted to 4,464,000 shares of the Company's common stock on November 1, 2014. The MLT members' deficit was transferred to stockholders' deficit on the accompanying balance sheets upon conversion to a C Corporation at that time.

Common Stock

The Company had 9,470,000 and 11,715,103 shares of its common stock issued and outstanding as of December 31, 2014 and June 30, 2015, respectively. Voting, dividend and liquidation rights of the holders

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of the common stock are subject to the Company's articles of incorporation, corporate bylaws and underlying shareholder agreements.

Dividend Rights

Common stock holders are entitled to receive dividends at the sole discretion of the board of directors of the Company. There have been no dividends declared on common stock as of June 30, 2015.

Voting Rights

The holders of common stock are entitled to one vote for each share of common stock along with all other classes and series of stock of the Company on all actions to be taken by the stockholders of the Company, including actions that would amend the certificate of incorporation of the Company to increase the number of authorized shares of the common stock.

Liquidation Rights

In the event of any liquidation, dissolution, or winding-up of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution post preferential distributions made to the Series A preferred stockholders.

9. Share-Based Compensation

The Company recognized $53,646 and $87,113 of share-based compensation related to employees and non-employees for the year ended December 31, 2014 and for the six months ended June 30, 2015, respectively, and was included in general and administrative expense in the accompanying statements of comprehensive loss.

Restricted Stock Awards

During the year ended December 31, 2014 and for the six months ended June 30, 2015, the Company granted an aggregate of 5,006,000 and 139,000 restricted stock awards (RSAs) to certain of its employees, members of its board of directors and consultants subject to a 2014 Shareholders Agreement (the Agreement). The RSAs are subject to various vesting schedules and generally vest ratably over a six to 24 month period coinciding with their respective service periods. During the year ended December 31, 2014 and the six months ended June 30, 2015, 1,903,819 and 1,088,583 RSAs vested, respectively, and no RSAs were forfeited during these periods.

The weighted average grant-date fair value of the RSAs issued during the year ended December 31, 2014 and for the six months ended June 30, 2015 was $140,168 and $9,313, respectively. Grant date fair market value was based on traditional valuation techniques and methods in determining the fair value of the Company's equity as a private company including market, income, and cost valuation approaches. A number of objective and subjective factors were considered including contemporaneous and retrospective valuations of its common stock performed by an unrelated valuation specialist, sales of the Company's convertible preferred stock to unrelated third parties, valuations of comparable peer public companies, the lack of liquidity of the Company's capital stock and general and industry-specific economic outlook. The fair value of the Company's common stock will be determined by the Company's board of directors until such time as the Company's common stock is listed on an established stock exchange.

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A summary of RSA grant activity is as follows:

	Number of Shares
Non-vested at December 31, 2013	—
Granted	5,006,000
Vested	(1,903,819)
Non-vested at December 31, 2014	3,102,181
Granted	139,000
Vested	(1,088,583)
Non-vested at June 30, 2015 (unaudited)	2,152,598

Stock Options

In April 2015, the Company adopted a 2015 Equity Incentive Plan (the 2015 Plan) under which 1,000,000 shares of the Company's common stock were reserved for issuance to employees, directors and consultants. The 2015 Plan permits the grant of incentive and non-statutory stock options, appreciation rights, restricted stock, restricted stock units, performance stock and cash awards, and other stock-based awards. Under this plan, 318,522 stock options were granted beginning on May 1, 2015 through June 29, 2015 and generally vest ratably over a two to 24 month period coinciding with their respective service periods. As of June 30, 2015, 681,478 shares were available for future issuance under the 2015 Plan. During the six months ended June 30, 2015, 116,072 stock options vested and no stock options were forfeited.

The Company measures the fair value of stock options with service-based and performance-based vesting criteria to employees, consultants and directors on the date of grant using the Black-Scholes option pricing model. The fair value of equity instruments issued to non-employees is re-measured as the award vests. The Company does not have history to support a calculation of volatility and expected term. As such, the Company has used a weighted-average volatility considering the volatilities of several guideline companies.

For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, and stage of life cycle. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The average expected life of the options was determined based on the mid-point between the vesting date and the end of the contractual term according to the "simplified method" as described in Staff Accounting Bulletin 110. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. Forfeitures are estimated based on the Company's historical analysis of both options and awards that forfeited prior to vesting.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows:

	Six months Ended June 30, 2015 (unaudited)
Expected stock price volatility	68.07%
Expected life of options (years)	5.23
Expected dividend yield	0%
Risk free interest rate	1.63%

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The following table summarizes the Company's stock option plan activity for the six months ended June 30, 2015 as follows (unaudited):

	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value[2]
Outstanding at December 31, 2014	—	—	—	—
Granted	318,522	$ 0.431	9.93	60,201
Exercised	—	—	—	—
Forfeited/Cancelled	—	—	—	—
Outstanding at June 30, 2015	318,522	$ 0.431	9.93	60,201
Vested and exercisable at June 30, 2015	116,072	$ 0.431	9.91	21,938
Vested and expected to vest at June 30, 2015[1]	318,522	$ 0.431	9.93	60,201

(1) Options that are expected to vest are net of estimated future option forfeitures in accordance with the provisions of ASC 718, *Compensation — Stock Compensation*

(2) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of our common stock as of June 30, 2015 of $0.62 per share

The weighted average fair value per share of options granted during the six month period ended June 30, 2015 was $0.25.

Unrecognized share-based compensation cost for the RSAs and stock options issued under the Agreement and the 2015 Plan was $159,251 (net of estimated forfeitures) as of June 30, 2015. Approximately $95,063 of the unrecognized compensation cost was related to the RSAs and $64,188 was related to the stock options. The non-employee portion of the unrecognized compensation cost was estimated utilizing the Company's fair market value for its common stock as of June 30, 2015. The unrecognized share-based expense is expected to be recognized over a weighted average period of 1.07 years for the RSAs and 0.81 years for the stock options.

10. Net Loss Per Common Share

Basic earnings or loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. The holders of the Series A preferred stock have rights to participation in common stock dividends, entitling the holders of Series A preferred stock to a dividend payable at the same time and rate per share as the dividend paid on common stock based the number of shares of common stock each share of Series A preferred stock would convert into if such shares had converted on the record date. The Series A preferred stock, however, does not have a contractual obligation to share in the losses of the Company, and as such, no losses were allocated to the Series A preferred stock for the purposes of the basic loss per share calculation. Prior to the Company's incorporation, no common shares were outstanding when the Company operated as MLT.

Diluted earnings or loss per share of common stock is computed similarly to basic earnings or loss per share except the weighted average shares outstanding are increased to include additional shares from the

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assumed exercise of any common stock equivalents, if dilutive. The Company's RSAs, stock options and shares of Series A preferred stock are considered common stock equivalents for this purpose. Diluted earnings is computed utilizing the treasury method, and in the case of the Series A preferred stock evaluation, the two-class method if more dilutive. No incremental common stock equivalents were included in calculating diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the year ended December 31, 2014 and for the six months ended June 30, 2015. The following table sets forth the computation of basic and diluted loss per share:

	Year Ended December 31, 2014	Six Months Ended June 31, 2015 (unaudited)
Numerator:		
Net loss	$ (320,212)	$ (3,890,286)
Adjustment for Series A preferred stock redemption value accretion	—	(2,666,232)
Net loss attributed to common stock holders	$ (320,212)	$ (6,556,518)
Denominator:		
Basic and diluted weighted average common shares outstanding	4,746,648	7,902,438
Basic and diluted net loss per share	$ (0.07)	$ (0.83)

The following potential common shares were not considered in the computation of diluted net loss per share as their effect would have been anti-dilutive:

	Year Ended December 31, 2014	Six Months Ended June 30, 2015 (unaudited)
Restricted stock awards	3,102,181	2,152,598
Stock options	—	318,522
Series A	—	2,325,581

11. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity specific measurement. Fair value is defined as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." Fair value measurements are defined on a three level hierarchy:

Level 1 inputs: Unadjusted quoted prices for identical assets or liabilities in active markets;

Level 2 inputs: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, weather directly or indirectly, for substantially the full term of the asset or liability;

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Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

As of December 31, 2013 and 2014 and June 30, 2015, the fair values of cash and cash equivalents, other assets, accounts payable and accrued liabilities approximated their carrying values because of the short-term nature of these assets or liabilities. The estimated fair value of the Company's Convertible Notes was based on amortized cost which was deemed to approximate fair value. The derivative liability associated with the conversion premium on the Convertible Notes was based on cash flow models discounted at current implied market rates evidenced in recent arms-length transactions representing expected returns by market participants for similar instruments which were based on Level 3 inputs. There were no transfers between fair value hierarchy levels for the year ended December 31, 2014 or during the six months ended June 30, 2015.

The fair value of financial instruments measured on a recurring basis is as follows:

	December 31, 2014			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Premium conversion derivative	$ 72,621	$ —	$ —	$ 72,621
Total liabilities at Fair Value	$ 72,621	$ —	$ —	$ 72,621

There were no financial instruments measured on a recurring basis as of December 31, 2013 or June 30, 2015.

There were no financial instruments measured on a non-recurring basis for any of the periods presented.

12. Income Taxes

The effective tax rate for the year ended December 31, 2014 and for the six month period ended June 30, 2015 was zero percent. MLT was treated as a partnership for federal and state income tax purposes. Accordingly, no provision was made for income taxes for periods prior to the merger, since the Company's net loss (subject to certain limitations) was passed through to the income tax returns of its members. Upon the incorporation of Gemphire on October 30, 2014, the Company became taxed as a corporation.

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A reconciliation of income tax computed at the statutory federal income tax rate to the provision (benefit) for income taxes included in the accompanying statements of comprehensive loss is as follows:

	Year Ended December 31, 2014	Six Months Ended June 30, 2015 (unaudited)
Income tax (benefit) provision at federal statutory rate	(34.0)%	(34.0)%
Non-benefited losses from valuation allowance	36.8	31.7
State income tax, net of federal benefit	(4.0)	(4.0)
Convertible notes	1.2	7.0
Other	—	(0.7)
Effective tax rate	—%	—%

Significant components of the Company's deferred tax assets and liabilities are summarized in the table below as of:

	December 31, 2014	June 30, 2015 (unaudited)
Deferred tax assets:		
Federal and state operating loss carryforwards	$ 92,623	$ 936,511
Acquired intangibles	—	344,575
Convertible notes	11,164	—
Charitable contributions	—	3,796
Accruals and reserves	—	11,465
Research and development credit carryforwards	114	29,484
	103,901	1,325,831
Valuation allowance	(72,046)	(1,303,160)
Total deferred tax assets, net of valuation allowance	31,855	22,671
Deferred tax liabilities:		
Restricted stock awards	(31,855)	(22,671)
Total deferred tax liabilities	(31,855)	(22,671)
Net deferred tax assets	$ —	$ —

As of December 31, 2014 and June 30, 2015, the Company had gross deferred tax assets of approximately $103,901 and $1.3 million, respectively. Realization of the deferred assets is primarily dependent upon future taxable income, if any, the amount and timing of which are uncertain. The Company has had significant pre-tax losses since its inception. The Company has not yet generated revenues and faces significant challenges to becoming profitable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance of $72,046 and $1.3 million as of December 31, 2014 and June 30, 2015, respectively. U.S. net deferred tax assets will continue to require a valuation allowance until the Company can demonstrate their realizability through sustained profitability or another source of income. Except for

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the Convertible Notes and a portion of the RSAs, the deferred tax assets and liabilities are non-current as of the dates reported.

As of December 31, 2014 and June 30, 2015, the tax effect of the Company's federal net operating loss carryforwards was approximately $82,961 and $838,814, respectively. The Company had federal research credit carryforwards as of December 31, 2014 and June 30, 2015, of approximately $114 and $29,484, respectively. The federal net operating loss and tax credit carryforwards will expire in 2034 if not utilized. As of December 31, 2014 and June 30, 2015, the Company had state net operating loss carryforwards of approximately $9,662 and $97,697, respectively. The Company did not have state research credit carryforwards as of December 31, 2014 and June 30, 2015. The state net operating loss carryforwards will expire in 2024 if not utilized.

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. Generally, in addition to certain entity reorganizations, the limitation applies when one or more "5-percent shareholders" increase their ownership, in the aggregate, by more than 50 percentage points over a 36-month time period testing period, or beginning the day after the most recent ownership change, if shorter. The annual limitation may result in the expiration of net operating losses and credits before utilization.

The Company recognizes interest and/or penalties related to uncertain tax positions in income tax expense. There were no uncertain tax positions as of December 31, 2014 and June 30, 2015, and as such, no interest or penalties were recorded to income tax expense.

The Company's corporate returns are subject to examination for the 2014 tax year in the federal and Michigan jurisdictions. Prior to this period, the Company filed partnership returns, resulting in its income being passed through to its members.

13. Related Party Transactions

The Company rented an office in Northville, Michigan from an LLC owned by an officer under a short-term agreement during the years ended December 31, 2013 and 2014 and the six months ended June 30, 2015. Rent expense under the related party agreement was $6,000 during each of the years ended December 31, 2013 and 2014 and $9,260 during the six month period ended June 30, 2015. A prepaid rent balance related to the short-term agreement amounted to $1,000 as of December 31, 2013, and $3,000 as of December 31, 2014 and June 30, 2015.

As of December 31, 2014, amounts owed to an officer and management team member of the Company under the Convertible Notes, inclusive of interest, were $315,710 and $48,171, respectively. In addition, amounts owed to an investor related to one of the Company's officers, inclusive of interest, as of December 31, 2014 under the Convertible Note were $25,077.

During the first quarter of 2015, the Company entered into $2.0 million of additional Convertible Notes (the 2015 Notes) as part of the Convertible Notes described in Note 4 — *Debt*. The 2015 Notes included four notes in the aggregate of $315,000 issued to investors who were related to one board member and three officers of the Company. On March 31, 2015, all of the Convertible Notes (including the 2015 Notes) were converted into 1,610,708 shares of Series A preferred stock. The conversion included a total of

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214,115 shares of Series A preferred stock issued to two officers of the Company, and 199,504 shares of Series A preferred stock issued to investors related to one board member and three officers of the Company.

14. Subsequent Events

The Company has evaluated subsequent events that may require adjustment to or disclosure in the financial statements and interim financial statements through September 10, 2015 for inclusion in the registration statement on Form S-1.

On July 31, 2015, the Company entered into a convertible interim note financing (the Interim Notes), pursuant to which certain investors agreed to loan the Company approximately $2.8 million. The Interim Notes accrue interest at a rate of 8% per annum, compounded annually, and would automatically convert into shares issued to investors in the Company's next equity financing round that results in gross proceeds of at least $5.0 million (a Qualified Financing). The conversion would be equal to unpaid principal at 115% plus any unpaid accrued interest. The investors would be paid out principal at 200% if a change of control occurred before the next financing round. In the event that a Qualified Financing, change of control, or an IPO does not occur before July 31, 2016, the parties would then negotiate a price for conversion into a new round of stock.

The Interim Notes included five notes issued to two officers and three board members (or entities they control) in the amount of $496,000. In addition, the Interim Notes included four notes to investors who were related to three of the Company's officers and to one of the Company's key employees in the amount of $250,000.

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Shares

Common Stock

PRELIMINARY PROSPECTUS

Joint Book-Running Managers

Jefferies
Cowen and Company

Co-Manager

Roth Capital Partners

, 2015

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by Gemphire Therapeutics Inc., or the Registrant, in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission (SEC), registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA), filing fee and the NASDAQ Global Market listing fee.

	AMOUNT TO BE PAID
SEC registration fee	$ *
FINRA filing fee	*
NASDAQ Global Market filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

The Registrant is incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who were, are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who were, are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorneys' fees) actually and reasonably incurred.

The Registrant's amended and restated certificate of incorporation provides for the indemnification of its directors to the fullest extent permitted under the Delaware General Corporation Law. The Registrant's amended and restated bylaws provide for the indemnification of its directors and officers to the fullest extent permitted under the Delaware General Corporation Law. Each of the Registrant's amended and restated certificate of incorporation and amended and restated bylaws will become effective upon the closing of this offering.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- § transaction from which the director derives an improper personal benefit;
- § act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- § unlawful payment of dividends or redemption of shares; or
- § breach of a director's duty of loyalty to the corporation or its stockholders.

The Registrant's amended and restated certificate of incorporation includes such a provision. Under the Registrant's amended and restated bylaws, expenses incurred by any director or officers in defending any such action, suit or proceeding in advance of its final disposition shall be paid by the Registrant upon delivery to it of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Registrant, as long as such undertaking remains required by the Delaware General Corporation Law.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption, may be held liable for such actions. A director who was either absent when the unlawful actions were approved or dissented at the time may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including reasonable attorneys' fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of Gemphire or any of its affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

There is at present no pending litigation or proceeding involving any of the Registrant's directors or executive officers as to which indemnification is required or permitted, and the Registrant is not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

The Registrant has an insurance policy in place that covers its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

The Registrant plans to enter into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify the Registrant's directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following sets forth information regarding all unregistered securities sold by the Registrant in the three years preceding the date of this registration statement:

1. Between March 2009 and October 2014, the Registrant borrowed an aggregate of $318,200 from, and issued promissory notes to, two of its executive officers. These promissory notes were refinanced in connection with the convertible promissory note financing discussed below. These transactions were exempt 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.

2. In November 2014, pursuant to the Plan and Agreement of Merger with Michigan Life Therapeutics, LLC, the Registrant granted 2,976,000 and 1,488,000 shares of common stock, respectively, to two of its executive officers. These transactions were exempt 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.

3. Between November 2014 and February 2015, the Registrant issued convertible promissory notes to 26 accredited investors, including the refinancing of two pre-existing promissory notes issued to two of its executive officers, for gross proceeds of approximately $2.7 million. These notes converted into an aggregate of 1,610,708 shares of the Registrant's Series A preferred stock in March 2015. These transactions were exempt 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.

4. Between November 2014 and February 2015, the Registrant granted stock awards for an aggregate of 5,145,000 shares of common stock to certain of its employees, consultants and directors. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act.

5. In March 2015, the Registrant issued an aggregate of 714,873 shares of Series A preferred stock to 18 accredited investors at $2.15 per share for an aggregate purchase price of approximately $1.5 million. These transactions were exempt 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.

6. In July 2015, the Registrant issued convertible promissory notes to 36 accredited investors in a private placement for gross proceeds of approximately $2.8 million. These transactions were exempt 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.

7. In March 2015, the Registrant issued 2,106,103 shares of its common stock to Pfizer Inc. pursuant to its exclusive license agreement with Pfizer Inc. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act.

8. Between May 2015 and August 2015, the Registrant granted stock options under its 2015 Plan to purchase an aggregate of 585,122 shares of common stock, with a weighted average exercise price of $0.544 per share, to certain of its employees, consultants and directors. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act.

The offers, sales and issuances of such stock awards and options were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 701 in that the transactions were under compensatory benefit plans or contracts relating to compensation as provided

under Rule 701. The recipients of such securities were employees, directors or bona fide consultants of the Registrant and received the securities under a compensatory contract or the Registrant's 2015 Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about the Registrant.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any general solicitation or advertising. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. Furthermore, the Registrant affixed appropriate legends to the share certificates and instruments issued in each of the foregoing transactions setting forth that the securities had not been registered under the Securities Act and the applicable restrictions on transfer.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1†	Form of Underwriting Agreement, including Form of Lock-Up Agreement.
3.1†	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2†	Form of Amended and Restated Certificate of Incorporation of the Registrant, effective immediately prior to the closing of this offering.
3.3†	Bylaws of the Registrant, as amended, as currently in effect.
3.4†	Form of Amended and Restated Bylaws of the Registrant, effective immediately prior to the closing of this offering.
4.1†	Form of Common Stock Certificate of the Registrant.
4.2†	Investor Rights Agreement, dated as of March 31, 2015, by and among the Registrant and the Investors listed therein.
5.1†	Opinion of Honigman Miller Schwartz and Cohn LLP.
10.1†*	Form of Indemnity Agreement.
10.2†*	2015 Equity Incentive Plan and Form of Grant Notice, Stock Option Agreement and Notice of Exercise thereunder.
10.3†*	Form of Amended and Restated 2015 Equity Incentive Plan, effective upon the execution and delivery of the underwriting agreement related to this offering.
10.4†*	Form of 2015 Employee Stock Purchase Plan, effective upon the execution and delivery of the underwriting agreement related to this offering.
10.5†*	Employee Agreement by and between the Registrant and Mina Sooch.
10.6†*	Employee Agreement by and between the Registrant and Charles L. Bisgaier.
10.7†*	Employee Agreement by and between the Registrant and David Lowenschuss.
10.8+	License Agreement, dated April 16, 2011, by and between the Registrant and Pfizer Inc.
10.9	Office Space Sublease Agreement, dated as of January 1, 2015, by and between the Registrant and Michigan Life Ventures, LLC, as amended on May 6, 2015 and August 31, 2015.
23.1†	Consent of Independent Registered Public Accounting Firm.
23.2†	Consent of Honigman Miller Schwartz and Cohn LLP. Reference is made to Exhibit 5.1
24.1†	Power of Attorney. Reference is made to the signature page hereto.

† To be filed by amendment.

* Indicates management contract or compensatory plan.

+ Registrant has omitted and filed separately with the SEC portions of the exhibit pursuant to a confidential treatment request under Rule 406 promulgated under the Securities Act.

(b) Financial Statement Schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

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 SEC 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 of 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:

(a) 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.

(b) 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, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Northville, State of Michigan, on the day of , 2015.

Gemphire Therapeutics Inc.

By: _____

Mina Sooch
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mina Sooch and David Lowenschuss, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
_____ Mina Sooch	President and Chief Executive Officer (Principal Executive, Financial and Accounting Officer)	, 2015
_____ Charles L. Bisgaier, Ph.D.	Chief Scientific Officer and Chairman of the Board of Directors	, 2015
_____ David Lowenschuss	Chief Legal Officer and Secretary	, 2015
_____ P. Kent Hawryluk	Member of the Board of Directors	, 2015

	Member of the Board of Directors	, 2015
Kenneth Kousky		
	Member of the Board of Directors	, 2015
Andrew Sassine		

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† To be filed by amendment.

* Indicates management contract or compensatory plan.

+ Registrant has omitted and filed separately with the SEC portions of the exhibit pursuant to a confidential treatment request under Rule 406 promulgated under the Securities Act.

Exhibit 10.8

LICENSE AGREEMENT

THIS LICENSE AGREEMENT ("**Agreement**") is made effective as of the 16th day of April, 2011 (the "Effective Date"), by and between Michigan Life Therapeutics, LLC a corporation organized and existing under the laws of Michigan with offices at 2020 Shadford Road, Ann Arbor, MI 48104 ("**LICENSEE**") and Pfizer Inc., a corporation organized and existing under the laws of Delaware with offices at 235 East 42nd Street, New York, NY 10017 ("**PFIZER**"). LICENSEE and PFIZER may, from time-to-time, be individually referred to as a "Party" and collectively referred to as the "Parties".

RECITALS

WHEREAS, PFIZER owns certain patents hereinafter referred and defined as License Patents; and

WHEREAS, LICENSEE wishes to obtain, and PFIZER wishes to grant, certain licenses relating to these License Patents on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. **DEFINITIONS**

1.1 "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "**control**" shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

1.2 "**Applicable Laws**" means all applicable laws, statutes, rules, regulations and guidelines, including, without limitation, all good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority.

1.3 "**Business Day**" means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York are authorized or required by law to remain closed.

1.4 "**Calendar Quarter**" means the three (3) month period commencing as of the Effective Date and each successive three (3) month period thereafter.

* Information redacted pursuant to a confidential treatment request by Gemphire Therapeutics Inc. under 5 U.S.C. §552(b)(4) and Rule 406 under the Securities Act of 1933 and submitted separately with the Securities and Exchange Commission.

1.5 "**Calendar Year**" means the twelve (12) month period commencing as of the Effective Date and each successive twelve (12) month period thereafter.

1.6 "**Commercialize**" or "**Commercialization**" means to manufacture for sale, market, promote, distribute, and sell.

1.7 "**Commercially Reasonable Efforts**" means: (a) with respect to the further Development of the Product, the efforts and expenditures required to obtain Regulatory Approvals and/or securing patents, that is comparable to any of LICENSEE's products that are at a similar stage of development, and (b) with respect to Commercialization of the Product, efforts and expenditures that are comparable to those used for any of LICENSEE's products that are of similar commercial potential.

1.8 "**Common Stock**" means shares of the common stock of the LICENSEE, par value $.01 per share.

1.9 "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a Permitted sublicense of or under such Intellectual Property Rights to the other Party without breaching the terms of any agreement with a Third Party.

1.10 "**Convertible Securities**" means any bonds, debentures, notes or other evidences of indebtedness, and any warrants, shares or any other securities convertible into, exercisable for, or exchangeable for Common stock, but excluding Options.

1.11 "**Develop**" or "**Development**" means to conduct any and all research and development activities necessary to obtain Regulatory Approval.

1.12 "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.13 "**First Commercial Sale**" means the first sale for use or consumption by the general public of the Product following receipt of Regulatory Approval for such Product from the US Federal Drug Authority or relevant foreign counterpart in the Territory.

1.14 "**Fully Diluted Shares**" means the number of shares of the Common Stock that are or would be issued and outstanding immediately following the issuance of all Subsequent Financing Securities *plus* all shares of Common Stock issuable upon conversion of all such Subsequent Financing Securities *plus* all shares of Common Stock that are issuable upon exercise or conversion of all other Options or Convertible Securities outstanding immediately following the issuance of all such Subsequent Financing Securities.

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1.15 "**GAAP**" means the generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board.

1.16 "**IND**" means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of the Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in the relevant regulatory jurisdictions in the Territory, as applicable.

1.17 "**Intellectual Property Rights**" means all trade secrets, copyrights, patents and other patent rights, Trademarks, moral rights, know-how and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.18 "**License Patents**" means any patents secured as listed in Schedule A and, the rights to use the Patents on the terms contained herein.

1.19 "**Milestone**" means each milestone as set forth in Section 5.1.2.

1.20 "**NDA/BLA**" means: (a) a new drug application or a new biologic license application filed with the FDA for authorization for marketing the Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.21 "**Net Sales**" means the consolidated gross amount of Licensed products invoiced by Licensee or any Affiliate, less sales returns, and allowances actually paid, granted or accrued, including trade, quantity and cash discounts, chargebacks, rebates, and customary trade discounts actually taken, outbound freight, value added tax, sales or use taxes, and custom or excise duties. Net sales shall be determined from the consolidated books and records of the Licensee and/or Affiliate of the Licensee, as the case maybe, and as maintained in accordance with the US. GAAP consistently applied.

The following principles shall apply in the calculation of Net Sales:

1.21.1 In the case of any sale of Product which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Product is paid for, if paid for before shipment or invoice.

1.21.2 In the case of any sale or other disposal of Product for non-cash consideration, Net Sales shall be calculated as the fair market price of the Product in the country of sale or disposal.

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1.21.3 Net Sales shall be reduced by [*] for sales of any Combination Products. For purposes of this Subsection 1.20.3, "Combination Products" means any pharmaceutical product containing: (a) the Product and (b) one or more other therapeutically active ingredient(s).

1.21.4 Unless otherwise specified herein, Net Sales shall be calculated in accordance with GAAP generally and consistently applied.

1.22 "**Options**" means rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

1.23 "**Patent Rights**" means: (a) the patents and patent applications listed in Schedule A, (b) all divisionals, continuations, and continuations-in-part that claim priority to the patents or patent applications described in subsection (a), (c) all patents that have issued or in the future issue from any of the foregoing patent applications in subsections (a) and (b), including utility, model and design patents and certificates of invention, (d) any reissues, renewals, extensions or additions of any of the foregoing, and (e) any foreign equivalents of any of the foregoing.

1.24 "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.25 "**Permitted sub licensee(s)**" means any third party, who is not an Affiliate of the Licensee, and in respect of whom, the Licensee has received prior written consent from Pfizer to assign any of its rights in the License Patents.

1.26 "**Product**" means Gemcabene calcium and further identified by CI-1027, PF-01430506, and/or PD-072953 ("Compound") along with certain intellectual property, information, and other related assets.

1.27 "**Regulatory Approval**" means, with respect to the Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Regulatory Authority to market and sell the Product in such country or jurisdiction.

1.28 "**Regulatory Authority**" means any governmental agency or authority responsible for granting Regulatory Approvals for the Product in the Territory.

1.29 "**Regulatory Filings**" means, with respect to the Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, NDA/BLA, any submission to a regulatory advisory

board, any marketing authorization application, and any supplement or amendment thereto.

1.30 "**Royalty Term**" means, with respect to the Product in each country in the Territory, the period commencing on the Effective Date and expiring upon the later of: the expiration or abandonment of the last Valid Claim of the Patent Rights, including any patent term extensions or supplemental protection certificates, in such country in the Territory.

1.31 "**Subsequent Financing Securities**" means shares of the LICENSEE'S Series A Preferred Stock or shares of any other convertible preferred equity security hereafter issued and sold by the LICENSEE (or to be issued and sold by the LICENSEE contingent upon the occurrence of any milestone or similar event, or upon the satisfaction of one or more conditions) in a bona fide, arm's length equity financing transaction with an unrelated third party.

1.32 "**Territory**" means the entire world.

1.33 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.34 "**Trademarks**" has the meaning as set forth in Section 13.6.5.

1.35 "**Use**" means to make, have made, use, sell, offer for sale, and import.

1.36 "**Valid Claim**" means either: (a) a claim of an issued and unexpired patent included within the Patent Rights, which has not been permanently revoked or declared unenforceable or invalid by an unreserved and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (b) a claim of a pending patent application included within the Patent Rights, which claim was filed in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

2. LICENSE GRANT

2.1 **License Grant of Patent Rights**.

Subject to the terms and conditions of this Agreement, PFIZER hereby grants to LICENSEE an exclusive, royalty-bearing right and license under the Patents Rights to Use the Product within the Territory Subject to the terms and conditions of this Agreement, PFIZER hereby grants to LICENSEE a royalty-bearing right and license to use the License Patents for the purpose of the Development and Commercialization of the Product in the within the Territory.

2.2 **Retained Rights**. LICENSEE acknowledges and agrees that PFIZER retains the right to make, have made and use the Product for any other purpose.

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2.3 **Residuals**. PFIZER may use for any purpose the Residuals resulting from access to or work with the Product and Know-How. As used herein, "Residuals" means information in non-tangible form which may be retained by persons who have had access to the Product and Know-How, including ideas, concepts, know-how or techniques contained therein.

2.4 **No Additional Rights**. Nothing in this Agreement shall be construed to confer any rights upon LICENSEE by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of PFIZER or its Affiliates other than the License Patents, regardless of whether such technology or Intellectual Property Rights shall be dominant or subordinate to any License Patents.

3. TRANSFER OF DOCUMENTATION

3.1 PFIZER agrees to maintain its currently existing records relating to the license Rights and Products, including regulatory records, for a period of six (6) months from the Effective Date. In the event that the LICENSEE wishes to access these, PFIZER will use reasonable efforts to: (a) make available to LICENSEE at the licensee's costs, currently available records which are with it on the Effective Date. The LICENSEE understands that the costs for such retrieval will be approximately [*] per day.

Notwithstanding the foregoing, in no event shall PFIZER provide: (a) data or records that include technology or products other than the Product, or (b) laboratory notebooks, PFIZER internal team meeting minutes, communications, personal notes or internal correspondence that are related to the Product, provided that PFIZER will provide to LICENSEE relevant summary information that pertains to subsections (a) and (b) to the extent such information: (x) exists as of the Effective Date, (y) is retained by PFIZER and (z) is reasonably retrievable by PFIZER.

4. DEVELOPMENT AND COMMERCIALIZATION

4.1 **Development**. LICENSEE shall itself, or through its Affiliates, use Commercially Reasonable Efforts to Develop the Product in the Territory. In connection with its efforts to develop the Product, LICENSEE shall bear all responsibility and expense for filing Regulatory Filings in LICENSEE's name and obtaining Regulatory Approval for the Product. LICENSEE will undertake such activities at its sole expense and shall provide to PFIZER reports regarding LICENSEE's progress within thirty (30) days following the expiration of each Calendar Year.

4.2 **Commercialization**. LICENSEE shall itself, or through its Affiliates or Permitted sub licensees, use Commercially Reasonable Efforts to Commercialize the Product in the Territory. LICENSEE will undertake such activities at its sole

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expense. It is expressly clarified that the Licensee shall be solely liable to meet or execute any and all compliances related to the manufacture, distribution or sale of the Licensed Products

4.3 **Payment Terms**.

4.3.1 In consideration of the licenses and rights granted to LICENSEE hereunder, LICENSEE shall pay to PFIZER payments in the following manner.

4.3.2 In partial consideration for the rights granted by PFIZER, the LICENSEE agrees that, upon the issuance of any Subsequent Financing Securities, or at any time at the request of PFIZER, the LICENSEE shall issue to PFIZER a number of shares of Common Stock equal to 15 percent of the LICENSEE'S Fully-Diluted Shares (such shares, the "Stock Consideration"). LICENSEE agrees that it shall take all such actions that are reasonably requested by Pfizer, or that are otherwise necessary or required, to give effect to the foregoing issuance of stock to PFIZER. LICENSEE represents and warrants to PFIZER that the Stock Consideration, when issued, and delivered in accordance with the terms hereof, will be duly and validly issued, fully-paid and non-assessable and will be issued in compliance with all applicable "federal and state securities laws regarding registration or qualification of such securities, and will not be issued in violation of any pre-emptive rights.

4.3.3 **Milestone Payments**. LICENSEE shall notify PFIZER as soon as practicable upon achievement of each Milestone. In further consideration of the licenses and rights granted to LICENSEE, within thirty (30) days upon achievement of each Milestone set forth below, LICENSEE shall pay to PFIZER the corresponding non-creditable and non-refundable milestone payment (each, a "Milestone Payment").

MILESTONE	MILESTONE PAYMENT
· Date of Regulatory Submission in any and first country in the Territory	$[*]
· Date of receipt of Regulatory Approval in the following countries	USA $[*] EU $[*] Japan $[*]
· One year Post Approval of the First received Regulatory Approval in any country in the Territory	$[*]

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MILESTONE	MILESTONE PAYMENT
· Sales Milestones	$[*] one-time payment upon achieving consolidated Net Sales of $[*]. $[*] one-time payment when first achieving consolidated Net Sales of $[*]. $[*] one-time payment when first achieving consolidated Net Sales of $[*]. $[*] one-time payment when first achieving consolidated Net Sales of $[*].

4.3.4 **Royalty Payments**.

(a) In consideration of the licenses and rights granted to the LICENSEE hereunder, LICENSEE shall pay to PFIZER the royalties set forth below on consolidated Net Sales of Product(s) in the Territory (collectively, "**Royalties**").

NET SALES	ROYALTY RATE
Net Sales equal to [*] per Calendar Year	[*] of Net Sales
Net Sales equal to [*] per Calendar Year	[*] of Net Sales
Net Sales equal or more than [*] per Calendar Year	[*] of Net Sales

(b) LICENSEE shall pay to PFIZER the applicable Royalties within thirty (30) days following the expiration of each Calendar Quarter after the date of the First Commercial Sale. Royalties will be payable on a country-by-country basis commencing as of the First Commercial Sale of a Product in each country until the expiration of the Royalty Term for such Product in each country.

(c) All payments shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation of Net Sales of Product (including all Deductions) and all Royalties payable to PFIZER for the applicable Calendar Quarter (including any foreign exchange rates employed).

(d) This Royalty shall be payable for the Royalty Term. It is expressly clarified that any and all fees, royalties, income or any direct or indirect benefit from association with the Permitted sublicense shall be valued and included for the purposes of

computing and ascertaining Milestone Payments and Royalties that shall be payable to PFIZER.

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4.3.5 **Other Payments**. LICENSEE shall pay to PFIZER any other amounts due under this Agreement within thirty (30) days following receipt of invoice.

4.3.6 **Late Payments**. Any late payments shall bear interest, to the extent permitted by law, at [*] on the date payment is due.

4.4 **Payment Method**.

4.4.1 Any payments under Section 5 that are recorded in currencies other than the US Dollar shall be converted into US Dollars at the average of the daily foreign exchange rates published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the Calendar Quarter in which such payments or expenses occurred, or for periods less than a Calendar Quarter, the average of the daily rates published in the Wall Street Journal for such period.

4.4.2 All payments from LICENSEE to PFIZER shall be made by wire transfer in US Dollars to the credit of such bank account as may be designated by PFIZER in writing to LICENSEE. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

4.5 **Taxes**.

4.5.1 It is understood and agreed between the Parties that any amounts payable by LICENSEE to PFIZER hereunder are exclusive of any and all applicable sales, use, VAT, GST, excise, property, and other taxes, levies, duties or fees (collectively, "**Taxes**"). LICENSEE shall be responsible for billing and collection from its customers and remitting to the appropriate taxing authority any and all Taxes which it is required to collect or remit. Each Party will be responsible for their own income and property taxes.

4.5.2 If LICENSEE is required to make a payment to PFIZER subject to a deduction of tax or withholding tax (a "**Withholding Tax Requirement**"), then the sum payable by LICENSEE (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that PFIZER receives a sum equal to the sum which it would have received had no such Withholding Tax Requirement been applicable, and the amount required to be deducted or withheld shall be remitted by LICENSEE in accordance with Applicable Law. Any such withholding taxes required under Applicable Law to be paid or withheld shall be an expense of, and borne solely by, LICENSEE.

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4.5.3 The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made by LICENSEE to PFIZER under this Agreement.

4.6 In the event that licensee is unable to adequately commercialize the Product or license Patents within a period of ten (10) years, PFIZER shall have the option of revoking the License Patents in its favor and/or that of its Affiliates. Any monies paid by the Licensee to PFIZER shall remain nonrefundable.

5. **RECORDS; AUDIT RIGHTS**

5.1 **Relevant Records**.

5.1.1 **Relevant Records**. LICENSEE shall maintain accurate financial books and records pertaining to and LICENSEE's sale of the Product, including any and all calculations of the applicable Fees (collectively, "**Relevant Records**"). LICENSEE shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) three (3) years following expiration or termination of this Agreement.

5.1.2 **Audit Request**. PFIZER shall have the right during the term and for twelve (12) months thereafter to engage, at its own expense, an independent auditor reasonably acceptable to LICENSEE to examine the Relevant Records from time-to-time, but no more frequently than once every twelve (12) months, as may be necessary to verify compliance with the terms of this Agreement. Such audit shall be requested in writing at least seven (7) days in advance, and shall be conducted during LICENSEE's normal business hours and otherwise in manner that minimizes any interference to LICENSEE's business operations.

5.1.3 **Audit Fees and Expenses**. PFIZER shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment of LICENSEE of more than [*] as to the period subject to the audit, LICENSEE shall reimburse PFIZER for any reasonable and documented out-of-pocket costs and expenses of the audit within thirty (30) days after receiving invoices thereof.

5.1.4 **Payment of Deficiency**. If any audit establishes that LICENSEE underpaid any amounts due to PFIZER under this Agreement, then LICENSEE shall pay PFIZER any such deficiency within thirty (30) days after receipt of written notice thereof. For the avoidance of doubt, such payment will be considered a late payment, subject to section 5.1.6.

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6. **INTELLECTUAL PROPERTY RIGHTS**

6.1 **Pre-existing IP**. Each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to or independent of this Agreement.

6.2 **Developed IP**. LICENSEE shall own all rights, title and interests in and to any Intellectual Property Rights that are both: (a) related to the Product, and (b) conceived solely by LICENSEE, its Affiliates or Permitted sub licensee's following the Effective Date (collectively, "**Developed IP**"). LICENSEE hereby grants to PFIZER a non-exclusive, sub licensable, royalty-free right and license under the Developed IP for any research or development purpose. For clarification purposes this license is a non-commercial license.

6.3 **Patent Prosecution**.

(a) Patent Prosecution and Maintenance. Subject to PFIZER's rights set forth below, LICENSEE will be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions and the like) and maintaining the Patent Rights in the Territory (and in PFIZER's name)at LICENSEE's own cost and expense. LICENSEE will select qualified patent counsel and corresponding foreign associates to prepare, file, prosecute and maintain the Patent Rights. LICENSEE will keep PFIZER reasonably informed of the status of the Patent Rights by timely providing PFIZER copies of significant communications relating to such Patent Rights that are received from any patent office or patent counsel of record or foreign associate.

Assistance.

As reasonably requested by PFIZER in writing, LICENSEE shall obtain patent term restoration at LICENSEE'S expense (under, but not limited to, the Drug Price Competition and Patent Term Restoration Act), supplementary protection certificates or their equivalents, and patent term extensions with respect to the Patent Rights in the United States, Japan and Europe.

(b) **Failure to Prosecute or Maintain**. In the event LICENSEE elects to forgo filing, prosecution or maintenance of the Patent Rights, LICENSEE shall notify PFIZER of such election at least forty-five (45) days prior to any filing or payment due date, or any other due date that requires action ("**Election Notice**"). Upon receipt of an Election Notice, PFIZER shall be entitled, upon written notice to LICENSEE, at its sole discretion and expense, to

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file or to continue the prosecution or maintenance of such Patent Right in such country in PFIZER's name using counsel of its own choice and at its own expense ("**Pfizer Patent Rights**"), in which case, the term "Patent Rights" shall be modified to exclude the Pfizer Patent Rights as of the date LICENSEE provides PFIZER such Election Notice.

7. **INFRINGEMENT; MISSAPPROPRIATION**

7.1 **Notification**. Each Party will promptly notify the other Party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any License Patents in the Territory of which it becomes aware ("**Third Party Infringement**").

7.2 **Infringement Action**.

7.2.1 **Right of First Enforcement**.

(a) LICENSEE shall have the first right (but not the obligation), at its own expense, to control enforcement of the License Patents against any Third Party Infringement. Prior to commencing any such action, LICENSEE shall consult with PFIZER and shall give due consideration to PFIZER's recommendations regarding the proposed action. LICENSEE shall give PFIZER timely notice of any proposed settlement of any such action instituted by LICENSEE and shall not, without the prior written consent of PFIZER, enter into any settlement that would: (i) adversely affect the validity, enforceability or scope of any of the Patent Rights, (ii) give rise to liability of PFIZER or its Affiliates, (iii) admit non-infringement of any Patent Rights, or (iv) otherwise impair PFIZER's rights in any License Patents or this Agreement.

(b) If LICENSEE does not obtain agreement from the alleged infringer to desist or fails to initiate an infringement action within: (i) sixty (60) days following LICENSEE's receipt of notice of the alleged infringement, or (ii) thirty (30) days before the expiration date for filing such actions, whichever comes first, PFIZER shall have the right, at its sole discretion, to control such enforcement of the License Patents at its sole expense.

7.2.2 **Recoveries.** Any recoveries resulting from an action relating to a claim of Third Party Infringement shall first be applied against payment of each Party's costs and expenses incurred in connection therewith

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(a) Any remaining recoveries shall be retained by (or if received by PFIZER, paid to) LICENSEE; provided however, PFIZER shall be entitled to a Royalty on such remaining recoveries at the applicable rate set forth herein as if the amount of such remaining recoveries were Net Sales of LICENSEE in the Calendar Year in which the recoveries were received by LICENSEE. If LICENSEE fails to institute an action or proceeding and PFIZER exercise its right to prosecute such infringement, any remaining recoveries shall be retained by PFIZER.

8. **CONFIDENTIALITY**

8.1 **Definition**. "**Confidential Information**" means the terms and provisions of this Agreement and other proprietary information and data of a financial, commercial or technical nature that the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, which are: (a) disclosed in writing or (b) if disclosed orally, summarized in writing and provided to the receiving Party after disclosure. All Know-How shall be considered PFIZER's Confidential Information.

8.2 **Obligations**. The receiving Party will protect all Confidential Information against unauthorized disclosure to Third Parties with reasonable degree of care. The receiving Party may disclose the Confidential Information to its Affiliates, and their respective directors, officers, employees, subcontractors, Permitted sublicense's, consultants, attorneys, accountants, banks and investors (collectively, "**Recipients**") who have a need-to-know such information for purposes related to this Agreement, provided that the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

8.3 **Exceptions**.

8.3.1 The obligations under this Section shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party;

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(c) is disclosed to the receiving Party on a non confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

8.3.2 The restrictions set forth in this Section shall not apply to any Confidential Information that the receiving Party is required to disclose under Applicable Laws or a court order or other governmental order, provided that the receiving Party: (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure and (c) if the disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel.

8.3.3 In the event that PFIZER wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, PFIZER may disclose to a Third Party Confidential Information of LICENSEE in connection with any such proposed assignment, provided that PFIZER shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

8.4 **Right to Injunctive Relief**. LICENSEE agrees that breaches of this Section may cause irreparable harm to PFIZER and shall entitle PFIZER, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

8.5 **Ongoing Obligation for Confidentiality**. Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one copy which may be retained in its confidential files for archive purposes.

9. **REPRESENTATIONS, WARRANTIES AND COVENANTS**

9.1 **Representations and Warranties by Each Party**. Each Party represents and warrants to the other Party as of the Effective Date that:

* Information redacted pursuant to a confidential treatment request by Gemphire Therapeutics Inc. under 5 U.S.C. §552(b)(4) and Rule 406 under the Securities Act of 1933 and submitted separately with the Securities and Exchange Commission.

(a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

(e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

9.2 **Representations and Warranties by LICENSEE**.

9.2.1 LICENSEE represents and warrants that it has the financial and commercial capabilities to Develop and Commercialize the Product in accordance with this Agreement.

9.2.2 LICENSEE represents and warrants to PFIZER that it shall comply with all Applicable Law with respect to the performance of its obligations hereunder.

9.2.3 Without limiting the generality contained herein, LICENSEE shall comply with the U.S. Foreign Corrupt Practices Act of 1977 (as modified or amended). LICENSEE represents and warrants that it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence any Government Official. If LICENSEE is itself a Government Official, LICENSEE represents and warrants that it has not accepted, and will not accept in the future, such a payment or transfer. As used herein, "Governmental Official" means: (a) any elected or appointed government

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official *(e.g.*, a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function, (c) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office, (d) an employee or person acting for or on behalf of a public international organization, or (e) any person otherwise categorized as a government official under local law. "**Government**" is meant to include all levels and subdivisions of non-U.S. governments *(i.e.*, local, regional, or national and administrative, legislative, or executive). LICENSEE will update these warranties if it or any of its employees, or a relative of such an individual, becomes a Government Official, or if a Government or Government Official becomes an owner of LICENSEE.

9.3 **No Other Warranties**. EXCEPT AS EXPRESSLY STATED HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OF THE LICENSED PRODUCT. ANY INFORMATION PROVIDED BY PFIZER OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

10. **INDEMNIFICATION**

10.1 **Indemnification by LICENSEE**. LICENSEE agrees to indemnify, hold harmless and defend PFIZER and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns (collectively, "**Pfizer Indemnitees**"), from and against any Claims arising or resulting from: (a) the Development of a Product by LICENSEE, its Affiliates (b) the Commercialization of a Product by LICENSEE, its Affiliates, subcontractors or Permitted sub licensees, (c) the negligence, recklessness or wrongful intentional acts or omissions of LICENSEE, its Affiliates, subcontractors or Permitted sub licensees, (d) breach by LICENSEE of any representation, warranty or covenant as set forth in this Agreement or (e) breach by LICENSEE of the scope of the license set forth in this Agreement. As used herein, "Claims" means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees).

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10.2 In the event of any non-compliance of any terms contained herein the LICENSEE hereby confirms and undertakes that any and all of its rights as provided herein in the Licensed Patents, including but not limited to all documents, materials or applications that maybe in possession or name of the Licensee or its Affiliate, shall be deemed to have been irrevocably transferred back to PFIZER, at no cost to PFIZER. Costs for such transfer shall be borne by the LICENSEE.

10.3 **Indemnification Procedure**. In connection with any Claim for which PFIZER seeks indemnification from LICENSEE pursuant to this Agreement, PFIZER shall: (a) give LICENSEE prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve LICENSEE from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with LICENSEE, at LICENSEE's expense, in connection with the defense and settlement of the Claim; and (c) permit LICENSEE to control the defense and settlement of the Claim; provided, however, that LICENSEE may not settle the Claim without PFIZER's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts PFIZER's rights or obligations. Further, PFIZER shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

11. LIMITATION OF LIABILITY

Consequential Damages Waiver. EXCEPT FOR A BREACH OF SECTION 9 OR OBLIGATIONS ARISING UNDER SECTION 10, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

12. TERM; TERMINATION

12.1 **Term**. The term of this Agreement shall commence as of the Effective Date and shall expire upon the last-to-expire Royalty Term.

12.2 **Termination for Cause**. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party breaches any of its material obligations hereunder and fails to cure such breach within thirty (30) days of receiving notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such thirty (30) day period, and the breaching Party initiates actions to

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cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed sixty (60) days. Any termination by a Party under this Section shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. For the avoidance of doubt, LICENSEE's failure to use Commercially Reasonable Efforts to Develop and Commercialize the Product shall constitute a material breach by LICENSEE under this Agreement.

12.3 **Termination for a Bankruptcy Event**. Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within ninety (90) days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of a Party's assets, or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

12.4 **Termination for Challenge to License Patents**. PFIZER shall have the right to immediately terminate this Agreement at any time after the Effective Date in its entirety or on a country-by-country basis in the event LICENSEE or any of its Affiliates or its or their Permitted sub licensees contests, challenges, supports or assists any Third Party to contest or challenge, in any patent office, court, regulatory agency or other forum, PFIZER's ownership of or rights in, or the validity, enforceability or scope of, any of the License Patents.

12.5 **Termination for Convenience**. LICENSEE shall have the right to terminate this Agreement for convenience upon ninety (90) days prior written notice to PFIZER. In the event LICENSEE terminates for convenience, LICENSEE shall pay to PFIZER an early termination fee in an amount equal to US Dollars [*].

12.6 **Effect of Termination or Expiration**.

12.6.1 Upon termination or expiration of this Agreement, LICENSEE shall pay to PFIZER all amounts due to PFIZER as of the effective date of termination or expiration within thirty (30) days following the effective date of termination or expiration.

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12.6.2 Upon termination of this Agreement, LICENSEE shall have the right to sell its remaining inventory of Product following the termination of this Agreement so long as LICENSEE has fully paid any and all Royalties, Milestone Payments and Permitted sublicense Fees owed to PFIZER, and LICENSEE otherwise is not in material breach of this Agreement.

12.6.3 Subject to this Section 12, upon termination of this Agreement, all licenses granted by PFIZER to LICENSEE shall terminate. For clarity, termination of the licenses granted by PFIZER to LICENSEE shall terminate all Permitted sublicenses granted by LICENSEE hereunder.

12.6.4 With the exception of termination of this Agreement by LICENSEE pursuant to Section 12.2, upon termination of this Agreement:

(a) LICENSEE hereby grants to PFIZER a non-exclusive, fully paid-up, royalty-free, worldwide, transferable, perpetual and irrevocable license, with the right to sublicense, to Use any Intellectual Property Rights Controlled by LICENSEE that arise from the Development or Commercialization of the Product, including without limitation, any and all Developed IP for Use of the Product.

(b) To the extent permitted by applicable Regulatory Authorities, LICENSEE shall: (i) transfer to PFIZER all Regulatory Filings and Regulatory Approvals held by LICENSEE with respect to the Product, and (ii) to the extent subsection (i) is not permitted by the applicable Regulatory Authority, permit PFIZER to cross-reference and rely upon any Regulatory Approvals and Regulatory Filings filed by LICENSEE with respect to the Product.

(c) LICENSEE hereby grants to PFIZER a fully paid-up, royalty-free, worldwide, transferable, sub licensable, perpetual and irrevocable license to use the Trademarks identifying a Product for the purpose of manufacturing, marketing, distributing and selling the Product. As used herein, "**Trademarks**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

(d) Upon PFIZER's request, LICENSEE shall continue all on-going Development for a mutually agreed upon migration period after termination of this Agreement, which period shall not be less than six (6) months unless otherwise agreed to by the Parties ("**Migration Period**"). During the Migration Period, LICENSEE shall provide such knowledge transfer and other training to

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PFIZER or its Affiliates or a Third Party that is designated in writing by PFIZER ("**Designated Affiliate/Third Party**") as reasonably necessary for PFIZER or the Designated Affiliate/Third Party to continue such activities. In connection with such transfer, LICENSEE shall, at PFIZER's option: (i) transfer to PFIZER or the Designated Affiliate/Third Party all Product at the cost paid by LICENSEE to manufacture such Product, (ii) transfer to PFIZER or the Designated Affiliate/Third Party all Licensee Inventory owned by LICENSEE at the cost paid by LICENSEE for such Licensee Inventory, and (iii) assign to PFIZER or the Designated Affiliate/Third Party any agreements with Third Parties with respect to the Development or Commercialization of the Product. As used herein, "**Licensee Inventory**" means all components and works in process produced or held by LICENSEE with respect to the manufacture of Products.

12.7 **Survival**. Expiration or termination of this Agreement shall not relieve the. Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 5, 6.1, 8, 10, 11, 12.6, 14, 15, 16.3 and 16.8 shall survive expiration or termination of this Agreement.

13. PUBLICITY

13.1 **Publicity**.

13.1.1 Subject to PFIZER's rights herein), neither Party (nor any of its Affiliates or agents) shall use the Trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance.

13.1.2 Each Party agrees not to issue any press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party, provided however, that neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law or the rules of any recognized stock exchange so long as the disclosing Party provides the other Party at least ten (10) Business Days prior written notice to the extent practicable and only discloses information to the extent required by Applicable Law or the rules of any recognized stock exchange.

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14. LICENSEE INSURANCE

14.1 **Insurance Requirements**. LICENSEE will maintain during the term of this Agreement and until the later of: (a) three (3) years after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Product have expired, commercial general liability insurance from a minimum "A-" AM Bests rated insurance company, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than [*] per occurrence and [*] in the aggregate. LICENSEE has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on LICENSEE's liability hereunder. Such policies shall name PFIZER and its Affiliates as additional insured and provide a waiver of subrogation in favor of PFIZER and

its Affiliates. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to PFIZER or its Affiliates. Any deductibles for such insurance shall be assumed by LICENSEE.

14.2 **Policy Notification**. LICENSEE shall provide PFIZER with certified copies of such policies or original certificates of insurance evidencing such insurance: (a) prior to execution by both Parties of this Agreement, and (b) prior to expiration of any one coverage. Such certificates shall provide that PFIZER shall be given at least thirty (30) days written notice prior to cancellation, termination or any change to restrict the coverage or reduce the limits afforded.

15. DISPUTE RESOLUTION

15.1 **General**. Except for disputes for which injunctive or other equitable relief is sought to prevent the unauthorized use or disclosure of proprietary materials or information or prevent the infringement or misappropriation of a Party's Intellectual Property Rights, the following procedures shall be used to resolve any dispute arising out of or in connection with this Agreement.

15.2 **Meeting**. Promptly after the written request of either Party, each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute. If the designated representatives do not resolve the dispute within sixty (60) Business Days of such request, then an executive officer of each Party shall meet in person or by telephone to review and attempt to resolve the dispute in good faith. The executive officers shall have sixty (60) Business Days to attempt to resolve the dispute.

16. GENERAL PROVISIONS

16.1 **Assignment**. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) PFIZER may assign to a Third Party its rights to receive some or all of the Fees

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payable hereunder, (b) each Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (c) either Party may assign this Agreement in the event of a Change in Control. As used herein, "**Change in Control**" means the acquisition of a party by a Third Party or the sale of all or substantially all of its business to which this Agreement relates. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.

16.2 **Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefore which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

16.3 **Governing Law; Exclusive Jurisdiction**.

16.3.1 This Agreement shall be governed by and construed under the laws in effect in the State of New York, US, without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result.

16.3.2 The courts of New York shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum, and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award.

16.4 **Force Majeure**. Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control

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of such Party (each, a "**Force Majeure Event**"), provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for one hundred eighty (180) days or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

16.5 **Waivers and Amendments**. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

16.6 **Relationship of the Parties**. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between PFIZER and LICENSEE, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

16.7 **Successors and Assigns**. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

16.8 **Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt), (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (receipt requested), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to PFIZER:

Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Fax: [*]
Attention: General Counsel

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If to LICENSEE:

Michigan Life Therapeutics, LLC
2020 Shadford Road
Ann Arbor, MI 48104
Fax: 734-864-5765
Attention: Dr. Charles Bisgaier

16.9 **Further Assurances**. LICENSEE and PFIZER hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

16.10 **No Third Party Beneficiary Rights**. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

16.11 **Entire Agreement; Confidentiality Agreement**.

(a) This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, without limitation, that certain Confidentiality Agreement by and between the Parties, dated October 28, 2008 and amendment dated January 29, 2009 ("**CDA**"). The Parties acknowledge and agree that, as of the Effective Date, all Evaluation Material (as defined in the CDA) disclosed by PFIZER or its Affiliates pursuant to the CDA shall be considered PFIZER's Confidential Information and subject to the terms set forth in this Agreement.

(b) In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

16.12 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

16.13 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

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16.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

[Signatures on next page]

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

MICHIGAN LIFE THERAPEUTICS, LLC

By: /s/ Charles L. Bisgaier

Name: Charles L. Bisgaier

Title: Chief Executive Manager
Michigan Life Therapeutics, LLC

PFIZER

By: /s/ Tim Rolph

Name: Tim Rolph

Title: VP, Pfizer Global Research
Head of CV, Metabolic and Endocrine

* Information redacted pursuant to a confidential treatment request by Gemphire Therapeutics Inc. under 5 U.S.C. §552(b)(4) and Rule 406 under the Securities Act of 1933 and submitted separately with the Securities and Exchange Commission.

SCHEDULE A: PATENT RIGHTS

1. PATENTS

Docket Number	Former Dkt No	Country	Application Number	Application Date	Status	Sub Status
[*]	[*]	[*]	[*]	[*]	[*]	[*]

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Exhibit 10.9

OFFICE SPACE SUBLEASE AGREEMENT

This OFFICE SPACE SUBLEASE AGREEMENT (this "**Agreement**") is dated and effective as of January 1, 2015 ("**Effective Date**"), by and **MICHIGAN LIFE VENTURES, LLC** a Michigan limited liability company with offices located at 43334 Seven Mile Road, Suite 100, Northville, MI 48167 ("**MLV**"), and, Gemphire Therapeutics Inc. a Delaware corporation with offices located at 43334 Seven Mile Road, Suite 1000, Northville, MI 48167 ("**GEMPHIRE**").

A. MLV has leased 1609sf of space at 43334 Seven Mile Road, Suite 1000, Northville, MI 48167 (the "MLV Space").

B. GEMPHIRE desires to use a portion of the MLV Space for the Permitted Use, as defined in **Section 3**. MLV is willing to allow GEMPHIRE to use a portion of the Building for such purpose upon the terms and conditions contained herein.

AGREEMENT

1. Description of Office Space Area. MLV hereby grants GEMPHIRE a sublease to use that portion of the MLV Space (including access to light and other utility switches and controls), as set forth in Exhibit A (the "**Office Space Area**"), for the Permitted Use (as defined in **Section 3)** and on the terms, covenants and conditions set forth herein. GEMPHIRE hereby accepts the Office Space Area on an "AS-IS" "WHERE-IS" basis, without any representation or warranty from MLV whatsoever with respect thereto.

2. Term and Termination. The term ("**Term**") of this Agreement shall commence on the Effective Date and shall terminate on June 30, 2015, unless this Agreement (i) is earlier terminated by MLV in accordance with **Section 10** of this Agreement or (ii) is extended by written amendment to this Agreement entered into by MLV and GEMPHIRE.

3. Permitted Use of Office Space Area. The Office Space Area may be used by GEMPHIRE in its business only for research and development of pharmaceuticals (the "**Permitted Use**").

4. Rent.

(a) "Gross rent" ("**Rent**") during the Term shall be $1,500.00 per month, commencing on January 1, 2015. For purposes of this Agreement, Rent shall include, but not be limited to, base rent, real estate property taxes and assessments, property insurance, operating expenses (including CAM), maintenance costs, management fees, snow removal and landscaping, phone and fax use, all utility costs and the use of all office equipment.

(b) As set forth above, Rent shall commence on January 1, 2015. Rent for the first quarter of the Term shall be due and payable within 30 days of the invoice date and thereafter shall be due and payable in full, in advance, on the first day of the beginning of each succeeding quarter during the Term. All payments of Rent shall be paid to Michigan Life

Ventures, LLC, 43334 Seven Mile Road, Suite 100, Northville, Michigan 48167.

5. Repairs/Maintenance/Utilities. During the Term, GEMPHIRE shall take good care of the Office Space Area, its appurtenances, fixtures and equipment, and shall not alter, drill into, disfigure or deface any part of the Office Space Area or the buildings, grounds or any part or portion of the Building of which the Office Space Area is a part without first obtaining MLV's written consent, which consent may be withheld in MLV's sole and absolute discretion but shall be reasonably given.

6. Assignment. GEMPHIRE shall not assign this Agreement or any interest in this Agreement or permit the use of the Office Space Area by any person or persons other than GEMPHIRE. Any attempted assignment shall void this Agreement.

7. Surrender. Upon the expiration or earlier termination of this Agreement, GEMPHIRE shall remove all personal property and other effects not belonging to MLV from the Office Space Area and shall leave the Office Space Area broom clean and otherwise in the condition received (ordinary wear and tear, casualty, obsolescence and acts of MLV excepted). Nothing contained herein shall be deemed to constitute MLV's agreement to allow GEMPHIRE to hold over.

8. [INTENTIONALLY OMITTED]

9. Security Deposit. MLV waives the payment of a security deposit by GEMPHIRE.

10. Default by GEMPHIRE. In the event that GEMPHIRE defaults under, or breaches, any or all of its obligations under this Agreement, MLV shall have the right to deliver a written notice to GEMPHIRE, terminating this Agreement and the Agreement granted to GEMPHIRE hereunder ("**Termination Notice**"), unless such default is cured by GEMPHIRE within thirty (30) days of its receipt of the Termination Notice (five (5) days in the case of any failure to pay Rent). Such termination shall be deemed immediate upon the expiration of such notice period.

11. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one and the same Agreement. Delivery of an executed counterpart of this Agreement by facsimile shall be equally as effective as delivery of an original executed counterpart.

12. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Michigan.

13. Signage. GEMPHIRE shall not affix any sign of any size or character to any portion of the Property, without prior written approval of MLV, which approval shall not be unreasonably withheld or delayed, and then only in accordance with the landlord's requirements. GEMPHIRE shall remove all signs of GEMPHIRE upon the expiration or earlier termination of this Lease and immediately repair any damage to either or both of the Property and the Premises caused by, or resulting from, such removal or the installation or existence of the signs.

IN WITNESS WHEREOF, MLV and GEMPHIRE have executed this Agreement as of the date first above written. Individuals signing on behalf of a principal warrant that they have the authority to bind their principals. This Agreement shall not be effective until an appropriate written consent hereto has been executed and delivered by Lessor.

Michigan Life Ventures, LLC

By: /s/ Charles Bisgaier
Charles Bisgaier, Ph.D.
Chief Executive Manager

Gemphire Therapeutics Inc.:

By: /s/ Mina Sooch
Mina Sooch

Its: CEO & President

EXHIBIT A

Office Space Area Description

(attached)

AMENDMENT NO. 1 TO OFFICE SPACE SUBLEASE AGREEMENT

This Amendment No. 1 to the Office Space Sublease Agreement dated effective May 6, 2015 (this "Amendment") is made by and between Gemphire Therapeutics Inc. ("GEMPHIRE") and Michigan Life Ventures, LLC ("MLV"). This Amendment amends the Office Space Sublease Agreement with an effective date of January 1, 2015, by and between GEMPHIRE and MLV (the "Agreement"). All capitalized terms not otherwise defined herein shall have the meanings ascribed thereto in the Agreement.

The parties want to amend the Agreement to extend the term of the Agreement through August 31, 2015, and because of the prepayment of rent no rent will be paid by Gemphire for the final two months of the lease term. Additionally, the parties obligations related to the cleaning of the offices is addressed.

The parties hereby amend the Agreement as follows:

1. Section 2 of the Agreement is amended by deleting the date "June 30, 2015" and replacing it with "August 31, 2015".
2. The parties agree that there will be no rent due and payable for the months of July and August of 2015 because of prepayment of rent by GEMPHIRE.
3. The parties agree that GEMPHIRE will be responsible for 60% of the cleaning fees incurred by MLV through the term of the Agreement and MLV will be responsible for 40% of these fees.

Except as amended hereby, the Agreement remains in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 by their duly authorized representatives effective the date set forth above.

Gemphire Therapeutics Inc.		**Michigan Life Ventures, LLC**	
By:	/s/ Mina Sooch	By:	/s/ Charles L. Bisgaier
Name:	Mina Sooch	Name:	Charles L. Bisgaier
Title:	CEO	Title:	Chief Executive Manager
	Duly Authorized		*Duly Authorized*
Date:	7-3-15	Date:	7-3-15

AMENDMENT NO. 2 TO OFFICE SPACE SUBLEASE AGREEMENT

This Amendment No. 2 to the Office Space Sublease Agreement dated effective August 31, 2015 (this "Amendment") is made by and between Gemphire Therapeutics Inc. ("GEMPHIRE") and Michigan Life Ventures, LLC ("MLV"). This Amendment amends the Office Space Sublease Agreement with an effective

date of January 1, 2015, by and between GEMPHIRE and MLV (the "Agreement"). All capitalized terms not otherwise defined herein shall have the meanings ascribed thereto in the Agreement.

The parties want to amend the Agreement to extend the term of the Agreement through September 30, 2015, extend the amount of office space to be occupied by GEMPHIRE and increase the amount of cleaning fees to be paid by GEMPHIRE.

The parties hereby amend the Agreement as follows:

1. The Office Space Area is increased to 90% of the MLV Space.
2. Section 2 of the Agreement is amended by deleting the date "August 31, 2015" and replacing it with "September 30, 2015".
3. Section 4.a. of the Agreement is amended by increasing the rent amount to be paid from $1,500.00 to $2,250.00 because of the increase in the Office Space Area.
4. The parties agree that GEMPHIRE will be responsible for 100% of the cleaning fees beginning September 1, 2015.

Except as amended hereby, the Agreement remains in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 2 by their duly authorized representatives effective the date set forth above.

Gemphire Therapeutics Inc.		**Michigan Life Ventures, LLC**	
By:	/s/ Mina Sooch	By:	/s/ Charles L. Bisgaier
Name:	Mina Sooch	Name:	Charles L. Bisgaier
Title:	President & CEO	Title:	Chief Executive Manager
	Duly Authorized		*Duly Authorized*
Date:	8/27/2015	Date:	8/25/2015