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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**Form 10-Q**

**(Mark One)**

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
**For the Quarterly Period Ended September 30, 2016**

**OR**

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF SECURITIES EXCHANGE ACT OF 1934  
**For the transition period from \_\_\_\_ to \_\_\_\_**

**Commission file number 001-37809**

**Gemphire Therapeutics Inc.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**47-2389984**

(IRS Employer Identification No.)

**17199 N. Laurel Park Drive, Suite 401, Livonia, MI**

(Address of principal executive offices)

**48152**

(Zip Code)

**(248) 681-9815**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12(b)-2 of the Securities Exchange Act of 1934). Yes   
No

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of October 25, 2016 was 9,270,255

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**Gemphire Therapeutics Inc.**  
**FORM 10-Q**  
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PART I – FINANCIAL INFORMATION  
ITEM 1 – FINANCIAL STATEMENTS**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Condensed Balance Sheets**  
**(in thousands, except share amounts and par value)**

	September 30, 2016 (unaudited)	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,369	\$ 3,620
Prepaid expenses	547	23
Total current assets	28,916	3,643
Deferred offering costs	—	847
Deposits	8	—
Total assets	\$ 28,924	\$ 4,490
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,257	\$ 531
Accrued liabilities	679	1,617
Convertible notes to related parties	—	1,795
Convertible notes	—	4,629
Premium conversion derivative	—	345
Total current liabilities	1,936	8,917
Total liabilities	1,936	8,917
Commitments and contingencies (Note 5)		
Series A convertible preferred stock, \$0.001 par value; no shares authorized as of September 30, 2016 and 2,325,581 shares authorized as of December 31, 2015, no shares issued or outstanding as of September 30, 2016 and 745,637 shares issued and outstanding as of December 31, 2015, aggregate liquidation preference as of September 30, 2016 and December 31, 2015 of zero and \$7,953, respectively.	—	7,953
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of September 30, 2016 and no shares authorized as of December 31, 2015, no shares issued or outstanding as of September 30, 2016 and December 31, 2015.	—	—
Common stock, \$0.001 par value; 100,000,000 and 17,674,419 shares authorized as of September 30, 2016 and December 31, 2015, respectively, 9,270,255 and 3,758,488 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively.	17	12
Additional paid-in capital	46,816	—
Accumulated deficit	(19,845)	(12,392)
Total stockholders' equity (deficit)	26,988	(12,380)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 28,924	\$ 4,490

See accompanying notes to condensed financial statements.

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Condensed Statements of Comprehensive Loss**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Operating expenses:				
General and administrative	\$ 1,466	\$ 997	\$ 3,567	\$ 2,130
Research and development	1,936	1,369	3,901	2,527
Acquired in-process research and development	—	—	—	908
Total operating expenses	3,402	2,366	7,468	5,565
Loss from operations	(3,402)	(2,366)	(7,468)	(5,565)
Interest (expense) income	(475)	(209)	101	(899)
Other (expense) income	(1)	6	(5)	5
Net loss	(3,878)	(2,569)	(7,372)	(6,459)
Other comprehensive loss, net of tax	—	—	—	—
Comprehensive loss	\$ (3,878)	\$ (2,569)	\$ (7,372)	\$ (6,459)
Net loss	\$ (3,878)	\$ (2,569)	\$ (7,372)	\$ (6,459)
Adjustment to redemption value on Series A convertible preferred stock	(67)	(152)	(366)	(2,818)
Net loss attributable to common stockholders	\$ (3,945)	\$ (2,721)	\$ (7,738)	\$ (9,277)
Net loss per share:				
Basic and diluted (Note 10)	\$ (0.56)	\$ (0.87)	\$ (1.65)	\$ (3.39)
Number of shares used in per share calculations:				
Basic and diluted	6,983,667	3,124,804	4,703,774	2,732,876

See accompanying notes to condensed financial statements.

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**(in thousands, except share amounts)**  
**(unaudited)**

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2015	—	\$ —	3,036,236	\$ 9	\$ 44	\$ (584)	\$ (531)
Issuance of convertible Series A preferred stock, net of issuance costs	745,637	4,985	—	—	—	—	—
Redemption value adjustment — Series A preferred stock	—	2,666	—	—	(1,131)	(1,687)	(2,818)
Issuance of common stock	—	—	675,250	2	906	—	908
Issuance of restricted stock awards	—	—	44,567	—	—	—	—
Share-based compensation — employee	—	—	—	—	82	—	82
Share-based compensation — non-employee	—	—	—	—	99	—	99
Net loss	—	—	—	—	—	(6,459)	(6,459)
Balance at September 30, 2015	<u>745,637</u>	<u>\$ 7,651</u>	<u>3,756,053</u>	<u>\$ 11</u>	<u>\$ —</u>	<u>\$ (8,730)</u>	<u>\$ (8,719)</u>
Balance at January 1, 2016	745,637	\$ 7,953	3,758,488	\$ 12	\$ —	\$ (12,392)	\$ (12,380)
Redemption value adjustment — Series A preferred stock	—	366	—	—	(285)	(81)	(366)
Conversion of Series A preferred stock to common stock	(745,637)	(8,319)	827,205	1	8,318	—	8,319
Separation of convertible note beneficial conversion feature upon contingency resolution	—	—	—	—	372	—	372
Conversion of convertible notes to common stock	—	—	1,656,807	1	11,444	—	11,445
Issuance of common stock from offering	—	—	3,027,755	3	30,275	—	30,278
Issuance costs of offering	—	—	—	—	(4,093)	—	(4,093)
Share-based compensation — employee	—	—	—	—	595	—	595
Share-based compensation — non-employee	—	—	—	—	190	—	190
Net loss	—	—	—	—	—	(7,372)	(7,372)
Balance at September 30, 2016	<u>—</u>	<u>\$ —</u>	<u>9,270,255</u>	<u>\$ 17</u>	<u>\$ 46,816</u>	<u>\$ (19,845)</u>	<u>\$ 26,988</u>

See accompanying notes to condensed financial statements.

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Condensed Statements of Cash Flows**  
**(in thousands)**  
**(unaudited)**

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating activities</b>		
Net loss	\$ (7,372)	\$ (6,459)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	785	181
Non-cash interest on convertible notes to related parties	146	21
Non-cash interest on convertible notes	256	50
Non-cash discount amortization on convertible notes to related parties	(17)	61
Non-cash discount amortization on convertible notes	(276)	260
Revaluation of premium conversion derivative	(850)	505
Non-cash interest upon conversion of convertible notes	649	—
Non-cash acquisition of in-process research and development	—	908
Change in assets and liabilities:		
Prepaid expenses and deposits	(532)	(12)
Accounts payable	347	56
Accrued liabilities	(556)	1,252
Net cash used in operating activities	<u>(7,420)</u>	<u>(3,177)</u>
<b>Investing activities</b>		
Net cash provided by (used in) investing activities	—	—
<b>Financing activities</b>		
Proceeds from issuance of convertible notes	2,651	3,705
Proceeds from issuance of convertible notes to related parties	2,500	1,061
Issuance costs related to convertible notes	(10)	—
Proceeds from issuance of Series A convertible preferred stock	—	1,522
Proceeds from offering	30,278	—
Offering costs	(3,250)	(77)
Net cash provided by financing activities	<u>32,169</u>	<u>6,211</u>
Net increase in cash and cash equivalents	24,749	3,034
Cash and cash equivalents at beginning of period	3,620	317
Cash and cash equivalents at end of period	<u>\$ 28,369</u>	<u>\$ 3,351</u>
<i>Supplemental disclosure of cash flow information:</i>		
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>
Cash paid for interest	<u>\$ —</u>	<u>\$ 2</u>
<i>Supplemental non-cash financing transactions:</i>		
Conversion of Series A preferred stock to common stock	<u>\$ 8,319</u>	<u>\$ —</u>
Conversion of convertible notes common stock	<u>\$ 11,445</u>	<u>\$ —</u>
Conversion of convertible notes to Series A preferred stock	<u>\$ —</u>	<u>\$ 2,778</u>
Exercise of premium conversion derivative	<u>\$ —</u>	<u>\$ 685</u>
Redemption value change of Series A preferred stock	<u>\$ 366</u>	<u>\$ 2,818</u>
Issuance of common stock for acquisition of in-process research and development	<u>\$ —</u>	<u>\$ 908</u>
Bifurcation of premium conversion derivative related to convertible notes	<u>\$ 505</u>	<u>\$ 502</u>
Separation of beneficial conversion feature associated with convertible notes	<u>\$ 372</u>	<u>\$ —</u>
Offering costs in accounts payable and accrued liabilities	<u>\$ 3</u>	<u>\$ 538</u>

See accompanying notes to condensed financial statements.

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Notes to Condensed Financial Statements (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. The Company's headquarters are located in Livonia, 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 and NAFLD/NASH (nonalcoholic fatty liver 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.

**Initial Public Offering**

On August 4, 2016, the Company's Registration Statement on Form S-1 (File No 333-210815) relating to its initial public offering ("IPO") of its common stock was declared effective by the Securities and Exchange Commission (SEC). Pursuant to such Registration Statement, on August 10, 2016, the Company closed its IPO whereby 3,000,000 shares of its common stock were issued and sold at a public offering price of \$10.00 per share. On September 8, 2016, the Company closed the sale of 27,755 shares of its common stock at the public offering price of \$10.00 per share, representing a partial exercise of the underwriters' over-allotment option, following which, the IPO terminated. The Company received net proceeds of approximately \$26.2 million after deducting underwriting discounts and commissions of \$2.1 million and other offering expenses of \$2.0 million.

Immediately prior to the IPO, the Company amended and restated its certificate of incorporation and bylaws to, among other things, change its authorized capital stock to consist of (i) 100,000,000 shares of common stock and (ii) 10,000,000 shares of undesignated preferred stock. Both the common stock and the preferred stock have a par value of \$0.001 per share.

**Basis of Presentation**

The accompanying condensed financial statements have been prepared by the Company, without audit, pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles (GAAP) have been condensed or omitted pursuant to such rules and regulations. The September 30, 2016 condensed balance sheet was derived from audited financial statements, and may not include all disclosures required by U.S. GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2015 included in the Company's final prospectus filed pursuant to Rule 424(b) with the SEC on August 8, 2016. The condensed balance sheet at December 31, 2015 was derived from the audited financial statements.

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Notes to Condensed Financial Statements (unaudited) - continued**

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 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.

Certain prior period balances have been reclassified to conform to the current period presentation. Specifically, the Company reclassified all current deferred tax liabilities as long term in the amount of \$10,000 on its December 31, 2015 condensed balance sheet in conformity with the adoption of Accounting Standards Update (ASU) 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* (ASU 2015-17).

**Reverse Stock Split**

In April 2016, the board of directors approved an amendment to the Company's certificate of incorporation to effect a 1-for-3.119 reverse stock split (the Reverse Stock Split) for all common and Series A preferred stock. The Reverse Stock Split became effective on April 27, 2016 upon the filing of the amendment to the certificate of incorporation. The authorized shares and par value of the common stock and Series A preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common and Series A preferred stock, options for common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

**2. Summary of Significant Accounting Policies**

**Use of Estimates**

The preparation of condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed 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 condensed financial instruments include principally cash and cash equivalents, other current assets, accounts payable, accrued liabilities and debt. The carrying amounts for these condensed 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, non-legal patent costs, fees paid

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Notes to Condensed Financial Statements (unaudited) - continued**

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.

**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, as a result of the early adoption of ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, the Company has made an accounting policy election to record forfeitures when they occur. 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 prior to the close of the IPO, 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 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 745,637 shares of Series A convertible preferred stock (the Series A preferred stock). On August 10, 2016, immediately prior to the closing of the IPO, the Company’s Series A preferred stock, together with accrued dividends thereon, converted into 827,205 shares of common stock. The Series A preferred stock prior to conversion was classified outside of permanent equity, in mezzanine equity, on the Company’s condensed balance sheet. The Company initially records preferred stock that may be redeemed at the option of the holder, or based

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Notes to Condensed Financial Statements (unaudited) - continued**

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 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. As a result of their conversion to common stock on August 10, 2016 as described above, no shares of Series A preferred stock were outstanding as of September 30, 2016.

**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 for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease and NAFLD/NASH. 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 itself 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.

**Recent Accounting Pronouncements**

In November 2015, the Financial Accounting Standards Board (FASB) issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* (ASU 2015-17). The new guidance simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 applies to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this ASU. For public entities, ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016 with earlier application permitted. The new guidance may be applied either prospectively or retrospectively to all periods presented. The Company adopted this standard effective April 1, 2016 on a retrospective basis for each period presented. The adoption of this standard did not have a material impact on the Company's financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments — Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The guidance affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. The guidance is effective in the first quarter of fiscal 2019. Early adoption is permitted for the accounting guidance on financial liabilities under the fair value option. The Company is currently evaluating the impact of the new guidance on its financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The objective of this update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods and is to be applied utilizing a modified retrospective approach. The Company is currently evaluating the new guidance to determine the impact it may have on its financial statements.

**Gemphire Therapeutics Inc.**  
**(Formerly Known as Michigan Life Therapeutics, LLC)**  
**Notes to Condensed Financial Statements (unaudited) - continued**

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This ASU simplifies the accounting for share-based payment award transactions including: income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted this standard effective July 1, 2016 on a retrospective basis for each period presented. The adoption of this standard did not have a material impact on the Company's financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Clarification of Certain Cash Receipts and Cash Payments*. The objective of this ASU is to eliminate the diversity in practice related to the classification of certain cash receipts and payments in the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. For public business entities, this ASU is effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted. The amendments in this update should be applied retrospectively to all periods presented, unless deemed impracticable, in which case, prospective application is permitted. The Company is currently evaluating the requirements of this new guidance and has not yet determined its impact on the Company's financial statements.

### 3. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	As of September 30, 2016	As of December 31, 2015
Accrued offering costs	\$ 193	\$ 575
Legal costs	32	234
Payroll	—	2
Other research and development expenses	293	759
Other general and administrative expenses	161	47
Total	<u>\$ 679</u>	<u>\$ 1,617</u>

### 4. Debt

#### Convertible Notes

The Company completed a series of convertible note financings with certain investors beginning on November 1, 2014 and ending on February 18, 2015 (the Convertible Notes), whereby a total of \$2.7 million was loaned to the Company, of which \$2.0 million 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 converted into shares of the Company's Series A preferred stock upon close of the Series A preferred stock financing on March 31, 2015. The conversion equaled 125% of the unpaid principal plus unpaid accrued interest on the Convertible Notes.

At the time of their issuance, the Convertible Notes contained a conversion premium with regard to the conversion into the Series A preferred stock. The Company determined that the redemption feature under the Convertible Notes qualified as an embedded derivative and was separated from its debt host. The bifurcation of the embedded derivative from its debt host resulted in a discount to the Convertible Notes. The discount was amortized to interest expense over the term of the Convertible Notes using the straight-line method. The embedded derivative was accounted for separately on a fair market value basis. The Company recorded the fair value changes of the premium conversion derivative to interest expense that amounted to \$0.4 million for the nine months ended September 30, 2015. As a result of their conversion into shares of Series A preferred stock on March 31, 2015 as described above, there were no Convertible Notes outstanding as of September 30, 2016.

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**Interim Notes**

On July 31, 2015, the Company entered into a convertible interim note financing (collectively with the notes issued in December 2015, February 2016 and April 2016, the Interim Notes), pursuant to which certain investors agreed to loan the Company approximately \$2.8 million. On August 10, 2016, immediately prior to the closing of the IPO, the Company's Interim Notes, together with accrued interest thereon, converted into 1,656,807 shares of common stock.

The Interim Notes accrued 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 did not occur before July 31, 2016, the parties would then negotiate a price for conversion into a new round of stock.

In December 2015, the Company amended the Interim Notes and certain investors agreed to loan the Company an additional \$2.7 million for a revised financing total of \$5.5 million. The Interim Notes continued to accrue interest at an 8% rate per annum compounded annually, but were amended to automatically convert into shares of the same class of the Company's next convertible preferred stock financing round (the Preferred Stock Financing). The conversion into shares issued in the Preferred Stock Financing would be equal to unpaid principal at 115% plus unpaid accrued interest. In the event that either a change of control occurs or the Company completes a public transaction which results in the Company's stockholders holding securities listed on a national securities exchange, including an IPO, before the Preferred Stock Financing, the Interim Notes, as amended, would automatically convert into shares of the Company's common stock at a conversion price of \$6.70585 per share (which represents the original issue price of the Series A preferred stock) based on 100% of outstanding principal and unpaid accrued interest. Lastly, if a Preferred Stock Financing, change of control, or public transaction did not occur before December 31, 2016, the parties agreed to then negotiate a conversion price into a new round of stock.

In February 2016, certain investors agreed to loan the Company an additional \$0.2 million for a revised financing total of \$5.6 million. The Interim Notes continued to accrue interest at an 8% rate per annum compounded annually, but were amended to automatically convert into shares of the same class of the Company's next Preferred Stock Financing. The conversion into shares issued in the Preferred Stock Financing would be equal to unpaid principal at 115% plus unpaid accrued interest. In the event that either a change of control occurs or the Company completes a public transaction which results in the Company's stockholders holding securities listed on a national securities exchange, including an IPO, before the Preferred Stock Financing, the Interim Notes, as amended, would automatically convert into shares of the Company's common stock at a conversion price of \$6.70585 per share (which represents the original issue price of the Series A preferred stock) as adjusted for the Reverse Stock Split (as defined below) based on 100% of outstanding principal and unpaid accrued interest. Lastly, if a Preferred Stock Financing, change of control, or public transaction did not occur before December 31, 2016, the parties agreed to then negotiate a conversion price into a new round of stock.

In April 2016, the Company amended the Interim Notes and certain investors agreed to loan the Company an additional \$5.0 million for a revised financing total, including Interim Notes previously issued, of \$10.6 million. The Interim Notes continued to accrue interest at an 8% rate per annum compounded annually, but were amended so that 125% of the unpaid principal and accrued interest, would automatically convert into shares of the same class of the Company's next convertible preferred stock financing round of at least \$5.0 million (the Qualified Financing). In the event that either a change of control occurs or the Company completes a public transaction which results in the Company's stockholders holding securities listed on a national securities exchange, including an IPO, before the Qualified Financing, 100% of outstanding principal and unpaid accrued interest on the Interim Notes, as amended, would automatically convert into shares of the Company's common stock at a conversion price of \$6.70585 per share, as adjusted for the Reverse Stock Split. Lastly, if a Qualified Financing, change of control, or public transaction did not occur, the Interim Notes would become payable on demand anytime after December 31, 2016. The Company incurred issuance costs related to the April 2016 financing in the amount of \$10,000. The Interim Notes were discounted for the issuance costs, and the discount was amortized to interest expense over their remaining term using the straight-line method.

At the time of their issuance, the Interim Notes contained a conversion premium with regard to the conversion into

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shares at the time of the next Qualified Financing. The Company determined that the redemption feature under the Interim Notes qualified as an embedded derivative and was separated from its debt host. The bifurcation of the embedded derivative from its debt host resulted in a discount to the Interim Notes. The discount was amortized to interest expense over the term of the Interim Notes using the straight-line method. The embedded derivative was accounted for separately on a fair market value basis. The fair value of the derivative associated with the Interim Notes was \$0.3 million at December 31, 2015 and was included as premium conversion derivative on the accompanying condensed balance sheets. As a result of the conversion of the Interim Notes, together with accrued interest thereon, into common stock immediately prior to the closing of the IPO, there was no premium conversion derivative outstanding as of September 30, 2016. The Company recorded the fair value changes of the premium conversion derivative associated with the Interim Notes to interest (expense) income that amounted to \$0.2 million and \$(0.1) million for the three months ended September 30, 2016 and 2015, respectively, and \$0.9 million and \$(0.1) million for the nine months ended September 30, 2016 and 2015, respectively.

As a result of their conversion to common stock on August 10, 2016 as described above, there were no Interim Notes outstanding as of September 30, 2016.

## **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 September 30, 2016, 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 were entitled to cumulative accruing dividends at a simple rate of 8% per year on the original issue price of the preferred stock of \$6.70585 per share, as adjusted for the Reverse Stock Split. The dividends effectively accrued daily on each share of preferred stock. The dividends were 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 believed that the Company was 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 were to be paid in shares of common stock at the conversion price for the Series A preferred stock in effect at that time, which was 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 were payable upon a contingent event, the Company did not record them in the accompanying condensed financial statements as of December 31, 2015; however, cumulative unpaid dividends for the Series A preferred stock totaled \$0.3 million as of December 31, 2015. On August 10, 2016, immediately prior to the closing of the IPO, the Company's Series A preferred stock, together with accrued dividends thereon, converted into 827,205 shares of common stock, and as such, there were no cumulative unpaid dividends for the Series A preferred stock as of September 31, 2016.

### ***Other Agreements***

Both cancellable and non-cancellable facility agreements were in place that provided for fixed monthly rent for the quarters ended September 30, 2016 and 2015. The total rent expense was \$16,000 and \$6,000 for the three months ended September 30, 2016 and 2015, respectively, and \$32,000 and \$15,000 for the nine months ended September 30, 2016 and 2015, respectively. In May 2016, the Company entered into a new lease agreement for its headquarters location, commencing in August 2016, for approximately 5,300 square feet. The initial term of the agreement is 3 years with an initial monthly base rent of approximately \$8,400. In conjunction with entering into the new lease agreement for its

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headquarters location, the Company cancelled its original Northville, Michigan lease agreement, as amended, effective August 31, 2016 and renegotiated a new cancellable lease agreement for limited use of office space in the Northville location that expires in September 2017.

## **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 its first arms-length Series A financing, which occurred on March 31, 2015.

The Company 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 675,250 shares of its common stock, at a fair market value of \$0.9 million, 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 September 30, 2016.

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 sublicenses 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 745,637 shares of Series A preferred stock at a per share price of \$6.70585, as adjusted for the Reverse Stock Split, 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. On August 10, 2016, immediately prior to the closing of the IPO, the Company's Series A preferred stock, together with accrued dividends thereon, converted into 827,205 shares of common stock.

Prior to their conversion into shares of common stock, the Series A preferred stock had the following rights and preferences:

### ***Dividend Rights***

Dividends effectively accrued on a daily basis at a simple rate of 8% per annum on the sum of the original per share issue price. Dividends were effectively deemed declared daily and were payable upon the occurrence of certain events. In addition, the holders of the Series A preferred stock had rights to participate in 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

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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 as of September 30, 2016 due to the conversion of the Series A preferred stock, together with accrued dividends thereon, on August 10, 2016 immediately prior to the closing of the IPO. There were no dividends deemed payable and accrued as of December 31, 2015, but unpaid dividends were \$0.3 million as of December 31, 2015. See Note 5 — *Commitments and Contingencies*.

***Voting Rights***

Each share of Series A preferred stock was 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 was 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, was not subject to a separate vote of the Series A preferred stockholders, but any subsequent increases to the authorized option pool were 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 was 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 were entitled to the assets of the Company legally available for distribution before any distribution or payment was made to the holders of common stock. The distribution amount would have been 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 would have been 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, could have been converted at any time into shares of common stock. The conversion rate would have been obtained by dividing the Series A preferred stock original issue price of \$6.70585 per share, as adjusted for the Reverse Stock Split, by the conversion price per share in effect at the time of conversion. The Series A conversion price was initially equal to the original issue price, but could be adjusted on a broad-based weighted average basis in connection with certain dilutive events. The Series A holder was also entitled to receive additional shares of common stock for any unpaid Series A dividends (whether or not declared).

Shares of Series A preferred stock would have automatically 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.

The conversion price for the Series A preferred stock was \$6.70585 per share (as adjusted for the Reverse Stock Split) at the time of the conversion of the Series A preferred stock, together with accrued dividends thereon, immediately prior to the closing of the IPO on August 10, 2016.

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***Redemption Rights***

The holders of at least 80% of the outstanding shares of Series A preferred stock could have required 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 was defined as an amount per share equal to \$6.70585, 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 could have at times been based on fair market value. The assumptions used in calculating the estimated fair market value at each reporting period represented the Company's best estimate, however, inherent uncertainties were involved. As a result, if factors or assumptions changed, the estimated fair value could have been materially different.

The Company recognized changes in the redemption value immediately as they occurred and adjusted the carrying amount of the instrument to equal the redemption value at the end of each reporting period since it was probable that the instruments would have become redeemable. In the absence of retained earnings, these charges were 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 was 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' Equity (Deficit)**

**Common Stock**

The Company had 9,270,255 and 3,758,488 shares of its common stock issued and outstanding as of September 30, 2016 and December 31, 2015, respectively. Voting, dividend and liquidation rights of the holders 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 September 30, 2016.

***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.

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**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.

**Deferred Offering Costs**

IPO offering costs of \$4.1 million, consisting of underwriting discounts and commissions, legal, accounting and other direct fees and costs, were initially capitalized and subsequently offset against the Company's IPO proceeds upon the close of the offering in August 2016. There were no deferred offering costs capitalized as of September 30, 2016. As of December 31, 2015, offering costs of \$0.8 million were capitalized.

**9. Share-Based Compensation**

Share-based compensation expense was included in general and administrative and research and development costs as follows in the accompanying condensed statements of comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
General and administrative	\$ 400	\$ 94	\$ 618	\$ 181
Research and development	167	—	167	—
Total share-based compensation	<u>\$ 567</u>	<u>\$ 94</u>	<u>\$ 785</u>	<u>\$ 181</u>

**Restricted Stock Awards**

During the three and nine months ended September 30, 2016, the Company did not grant any restricted stock awards (RSAs). During the three and nine months ended September 30, 2015, the Company granted an aggregate of zero and 44,567 RSAs, respectively, 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 three and nine months ended September 30, 2016, 66,996 and 338,870 RSAs vested, respectively and no RSAs were forfeited during these periods. During the three and nine months ended September 30, 2015, 171,035 and 520,052 RSAs vested, respectively, and no RSAs were forfeited during these periods.

The grant-date fair value of the RSAs issued during the nine months ended September 30, 2015 was \$9,000. 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 was determined by the Company's board of directors prior to the IPO.

**Stock Options**

In April 2015, the Company adopted a 2015 Equity Incentive Plan (the 2015 Plan) under which 320,615 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.

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*Amendment and Restatement of 2015 Equity Incentive Plan*

In April 2016 the Company's board of directors approved the Company's amended and restated 2015 Plan (the A&R 2015 Plan). The Company's stockholders also approved the A&R 2015 Plan in April 2016 and the A&R 2015 Plan became effective immediately upon the execution and delivery of the underwriting agreement related to the IPO. The A&R 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity awards, as well as performance cash awards. The Company initially reserved 2,400,000 shares of common stock for issuance under the A&R 2015 Plan.

During the three and nine months ended September 30, 2016, the Company granted an aggregate of 1,825,200 stock options to its officers, directors, employees and consultants, generally vesting over a four-year period, with an exercise price equal to \$10 per share in connection with the pricing of the IPO. During the three and nine months ended September 30, 2015, 136,778 and 238,908 stock options, respectively, were granted.

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. As a result of the early adoption of ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, the Company has made an accounting policy election to record forfeitures when they occur.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows:

	Three Months Ended September 30.		Nine Months Ended September 30.	
	2016	2015	2016	2015
Expected stock price volatility	71.3%	72.4%	71.3%	70.7%
Expected life of options (years)	6.0	5.7	6.0	5.5
Expected dividend yield	0%	0%	0%	0%
Risk free interest rate	1.2%	1.7%	1.2%	1.7%

During the three and nine months ended September 30, 2016, 62,222 and 125,714 stock options vested, respectively, and no stock options were forfeited. During the three and nine months ended September 30, 2015, 39,019 and 76,234 stock options vested and no stock options were forfeited. As of September 30, 2016, 269,522 shares were available for future issuance under the A&R 2015 Plan.

Unrecognized share-based compensation cost for the RSAs and stock options issued under the Company's 2014 Shareholders Agreement and the A&R 2015 Plan was \$11.3 million as of September 30, 2016. Approximately \$11.3 million of the unrecognized compensation cost was related to the stock options and \$10,000 related to the RSAs. The non-employee portion of the unrecognized compensation cost was estimated utilizing the Company's fair market value for its common stock as of September 30, 2016. The unrecognized share-based expense is expected to be recognized over a weighted average period of 3.4 years for the stock options and 0.3 years for the RSAs.

*Inducement Plan*

In September 2016 the Company's board of directors approved the Company's Inducement Plan (the Inducement Plan). The Company initially reserved 300,000 shares of its common stock to be used exclusively for grants of awards to

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individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. The Plan was approved by the Company's board of directors without stockholder approval pursuant to Rule 5635(c)(4), and the terms and conditions of the Plan are substantially similar to the Company's stockholder-approved A&R 2015 Plan.

*Adoption of 2016 Employee Stock Purchase Plan*

In April 2016 the Company's board of directors approved the 2016 Employee Stock Purchase Plan (the ESPP) in order to enable eligible employees to purchase shares of the Company's common stock at a discount following the effective date of the IPO. The Company's stockholders also approved the ESPP in April, 2016 and the ESPP became effective immediately upon the execution and delivery of the underwriting agreement related to the IPO. The Company initially reserved 150,000 shares of common stock for issuance under the ESPP. As of September 30, 2016, no shares were purchased under the ESPP.

**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 had rights to participate 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 have converted into if such shares had converted on the record date. The Series A preferred stock, however, did 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 while they were outstanding. 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 assumed exercise of any common stock equivalents, if dilutive. The Company's RSAs, stock options, shares of Series A preferred stock, Convertible Notes and Interim Notes are considered common stock equivalents while outstanding for this purpose. Diluted earnings is computed utilizing the treasury method for the RSAs and stock options, and in the case of the Series A preferred stock, either the two-class method or the if-converted method, whichever was more dilutive. Diluted earnings with respect to the Convertible Notes and Interim Notes utilized the if-converted method, but was not applicable during the three and nine months ended September 30, 2016 and 2015 as no conditions required for conversion had occurred during these periods while the instruments were outstanding. 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 three and nine months ended September 30, 2016 and 2015. The following table sets forth the computation of basic and diluted loss per share as of September 30, 2016 and 2015 (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	\$ (3,878)	\$ (2,569)	\$ (7,372)	\$ (6,459)
Adjustment for Series A preferred stock redemption value accretion	(67)	(152)	(366)	(2,818)
Net loss attributed to common stock holders	<u>\$ (3,945)</u>	<u>\$ (2,721)</u>	<u>\$ (7,738)</u>	<u>\$ (9,277)</u>
Denominator:				
Basic and diluted weighted average common shares outstanding	6,983,667	3,124,804	4,703,774	2,732,876
Basic and diluted net loss per share	<u>\$ (0.56)</u>	<u>\$ (0.87)</u>	<u>\$ (1.65)</u>	<u>\$ (3.39)</u>

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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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Restricted stock awards	9,222	519,125	9,222	519,125
Stock options	2,130,478	238,908	2,130,478	238,908
Series A	—	745,637	—	745,637

**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, whether directly or indirectly, for substantially the full term of the asset or liability;

**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 September 30, 2016 and December 31, 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 Interim Notes was based on amortized cost which was deemed to approximate fair value. The derivative liability associated with the conversion premium on the Interim 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 during the three and nine months ended September 30, 2016 and 2015.

The fair value of financial instruments measured on a recurring basis is as follows (in thousands):

Description	As of December 31, 2015			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Premium conversion derivative	\$ 345	\$ —	\$ —	\$ 345
Total liabilities at Fair Value	<u>\$ 345</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 345</u>

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The following table provides a roll-forward of the Company's premium conversion derivative liabilities measured at fair value on a recurring basis using unobservable level 3 inputs (in thousands):

	For the Nine Months Ended September 30,	
	2016	2015
Balance as of beginning of period	\$ 345	\$ 73
Issuance of underlying convertible notes	505	502
Change in fair value of premium conversion derivative	(850)	505
Redemption of underlying convertible notes	—	(685)
Balance as of end of period	\$ —	\$ 395

There were no financial instruments measured on a recurring basis as of September 30, 2016 and on a non-recurring basis for any of the periods presented.

## 12. Income Taxes

The effective tax rate for the three and nine months ended September 30, 2016 and 2015 was zero percent. As a result of the analysis of all available evidence as of September 30, 2016 and December 31, 2015, the Company recorded a full valuation allowance on its net deferred tax assets. Consequently, the Company reported no income tax benefit for the three or nine month period ended September 30, 2016, or for the comparable periods in 2015. If the Company's assumptions change and the Company believes that it will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be recognized as a reduction of future income tax expense. If the assumptions do not change, each period the Company could record an additional valuation allowance on any increases in the deferred tax assets.

## 13. Related Party Transactions

The Company rented an office in Northville, Michigan from an LLC owned by two officers under short-term agreements during the three and nine month periods ended September 30, 2016 and 2015. The original facility lease, as amended, was cancelled and replaced with a cancellable lease agreement in August 2016 for limited use of office space in the same Northville location. The new lease agreement became effective in August 2016 and expires in September 2017 with a nominal base rent over its term. Rent expense under the related party agreements was \$5,000 and \$6,000 during the three months ended September 30, 2016 and 2015, respectively, and \$21,000 and \$15,000 during the nine months ended September 30, 2016 and 2015, respectively. A prepaid rent balance related to the short-term agreements amounted to \$3,000 as of December 31, 2015.

During the first quarter of 2015, the Company issued \$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 \$0.3 million 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 516,421 shares of Series A preferred stock. The conversion included a total of 68,649 shares of Series A preferred stock issued to two officers of the Company, and 63,967 shares of Series A preferred stock issued to investors related to one board member and three officers of the Company.

During the third quarter of 2015, the Company issued \$2.8 million of Interim Notes as described in Note 4 — *Debt*. Such Interim Notes included five notes issued to two officers and three board members (or entities they control) in the amount of \$0.5 million. In addition, such 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 \$0.3 million.

In December 2015, the Company issued an additional \$2.7 million of Interim Notes, as described in Note 4 — *Debt*, which included six notes issued to two officers and four board members in the amount of \$0.6 million. The December 2015 Interim Note issuances also included five notes to investors who were related to three of the Company's officers in the amount of \$0.2 million.

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In February 2016, the Company issued an additional \$0.2 million of Interim Notes, as described in Note 4 — *Debt*, which included two notes issued to two board members (or entities they control) in the amount of \$81,000. The February 2016 Interim Note issuances also included a \$20,000 note to an investor who is related to an officer of the Company.

In April 2016, the Company issued an additional \$5.0 million of Interim Notes, as described in Note 4 — *Debt*, which included two notes to investors who were related to two of the Company's officers in the aggregate amount of \$0.2 million. The April 2016 Interim Notes issuances also included three notes to investors who were related to three of the Company's directors in the aggregate amount of \$2.3 million.

The IPO included 154,450 shares sold to 5 officers and 3 board members, totaling \$1.5 million. In addition, 500,000 shares were sold to 1 investor who is related to 1 of the Company's directors, totaling \$5.0 million, and 47,000 shares totaling \$0.5 million were sold to 14 investors who are related to 5 officers of the Company.

**ITEM 2 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes included in Part I "Financial Information", Item I "Financial Statements" of this Quarterly Report on Form 10-Q and the audited financial statements and related footnotes included in our final prospectus filed pursuant to Rule 424(b) with the SEC on August 8, 2016.*

**Forward-Looking Statements**

*Certain statements contained in this Quarterly Report on Form 10-Q are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements give current expectations or forecasts of future events or our future financial or operating performance. 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.*

These forward-looking statements reflect our management's beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this report and are subject to risks and uncertainties, many of which are beyond our control, that could cause our actual results to differ materially from those in these forward-looking statements. We discuss many of these risks in greater detail under Part II, Item 1A "Risk Factors" in this report and subsequent reports filed with or furnished to the SEC. 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.

Any forward-looking statement made by us in this report speaks only as of the date hereof or as of the date specified herein. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable laws or regulations.

**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 and NAFLD/NASH (nonalcoholic fatty liver 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 mechanism of action is designed to enhance the clearance of VLDLs in the plasma and inhibit the production of fatty acids and cholesterol in the liver. 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, HeFH, ASCVD and SHTG. We believe we can design an efficient development plan to provide a new treatment alternative for HoFH 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 next twelve months, we expect to initiate three late stage clinical trials for gemcabene in HoFH, hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins, and

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SHTG. Upon completion of one or more of these clinical 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.

In April 2016, our board of directors approved an amendment to our certificate of incorporation to effect a 1-for-3.119 reverse stock split (the Reverse Stock Split) for all common and Series A preferred stock. The Reverse Stock Split became effective on April 27, 2016 upon the filing of the amendment to the certificate of incorporation. The authorized shares and par value of the common stock and Series A preferred stock were not adjusted as a result of the Reverse Stock Split.

On August 4, 2016, our Registration Statement on Form S-1 (File No 333-210815) relating to our initial public offering (“IPO”) of our common stock was declared effective by the Securities and Exchange Commission. Pursuant to such Registration Statement, on August 10, 2016, we closed our IPO whereby 3,000,000 shares of our common stock were sold at a public offering price of \$10.00 per share. On September 8, 2016, we closed the sale of 27,755 shares of our common stock at the public offering price of \$10.00 per share, representing a partial exercise of the underwriters’ over-allotment option, following which, the IPO terminated. We received net proceeds of approximately \$26.2 million after deducting underwriting discounts and commissions of \$2.1 million and other offering expenses of \$2.0 million.

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. Through September 30, 2016, we have funded our operations primarily through the IPO, totaling \$30.3 million in gross proceeds, and the issuance of preferred stock and convertible notes, totaling \$14.8 million in gross proceeds. Our net losses were \$3.9 million and \$7.4 million during the three and nine months ended September 30, 2016, respectively, as compared to \$2.6 million and \$6.5 million during the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of \$19.8 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;
- 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;

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- 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, significantly increased share-based compensation costs related to stock options issued in conjunction with our IPO and anticipated future option grants in conjunction with personnel additions, 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.

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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 in the future 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, 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) Income***

Interest (expense) income consists of interest (expense) income activity related to the Convertible Notes and Interim Notes, activity associated with the underlying premium conversion derivative related to such notes, and interest earnings from cash and cash equivalents. The notes we issued had an annual interest rate of 8%. The interest on the Interim Notes compounded on an annual basis while the interest on the Convertible Notes compounded daily. The principal and accrued and unpaid interest on the Convertible Notes converted into shares of the Company’s Series A preferred stock upon the closing of the Series A preferred stock financing on March 31, 2015, which shares of Series A preferred stock, and accrued dividends thereon, converted into common stock immediately prior to the closing of the IPO. The principal

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and accrued and unpaid interest on the Interim Notes converted into shares of common stock immediately prior to the closing of the IPO.

We expect to earn interest income in future periods from the investment of the net proceeds from the IPO and a significant decrease in interest (expense) income given the conversion of the principal and accrued and unpaid interest on both the Convertible Notes and Interim Notes.

**Other (Expense) Income**

Other (expense) income 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 September 30, 2016 and December 31, 2015.

**Results of Operations**

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

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2016	2015	Change	2016	2015	Change
	(in thousands)					
Operating expenses:						
General and administrative	\$ 1,466	\$ 997	\$ 469	\$ 3,567	\$ 2,130	\$ 1,437
Research and development	1,936	1,369	567	3,901	2,527	1,374
Acquired in-process research and development	—	—	—	—	908	(908)
Total operating expenses	<u>3,402</u>	<u>2,366</u>	<u>1,036</u>	<u>7,468</u>	<u>5,565</u>	<u>1,903</u>
Loss from operations	(3,402)	(2,366)	(1,036)	(7,468)	(5,565)	(1,903)
Interest (expense) income	(475)	(209)	(266)	101	(899)	1,000
Other (expense) income	(1)	6	(7)	(5)	5	(10)
Net loss	<u><u>\$ (3,878)</u></u>	<u><u>\$ (2,569)</u></u>	<u><u>\$ (1,309)</u></u>	<u><u>\$ (7,372)</u></u>	<u><u>\$ (6,459)</u></u>	<u><u>\$ (913)</u></u>

**Comparison of Three Months Ended September 30, 2016 and 2015**

*General and Administrative*

General and administrative expenses for the three months ended September 30, 2016 were \$1.5 million compared to \$1.0 million for the three months ended September 30, 2015. The \$0.5 million increase was primarily attributable to an increase in staffing and professional services. General and administrative expenses included \$0.4 million and \$94,000 in share-based compensation expense during the three months ended September 30, 2016 and 2015, respectively.

*Research and Development*

Research and development expenses for the three months ended September 30, 2016 were \$1.9 million compared to \$1.4 million for the three months ended September 30, 2015. The \$0.6 million increase was primarily attributable to the

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timing of 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. Research and development expenses included \$0.2 million in share-based compensation expense during the three months ended September 30, 2016. There was no share-based compensation expense during the three months ended September 30, 2015.

*Acquired In-process Research and Development*

No acquired in-process research and development expenses were incurred during each of the three month periods ended September 30, 2016 and 2015.

*Interest (Expense) Income*

Interest (expense) income for the three months ended September 30, 2016 and 2015 was \$(0.5) million and \$(0.2) million, respectively. The \$0.3 million net increase in interest expense, primarily non-cash, was due largely to the conversion of the Interim Notes to common stock and amortization of the beneficial conversion premium associated with the Interim Notes. Some of the increase in interest expense was offset by non-cash fair value adjustments associated with the underlying Interim Note premium conversion liability and by a small amount of interest earnings of \$9,000 from IPO cash proceeds. The principal and accrued and unpaid interest on the Interim Notes converted to common stock on August 10, 2016 immediately prior to the closing of the IPO, and as a result, no Interim Notes were outstanding as of September 30, 2016.

**Comparison of the Nine Months Ended September 30, 2016 and 2015**

*General and Administrative*

General and administrative expenses for the nine months ended September 30, 2016 were \$3.6 million compared to \$2.1 million for the nine months ended September 30, 2015. The \$1.4 million increase was primarily attributable to an increase in staffing and professional services. General and administrative expenses included \$0.6 million and \$0.2 million in share-based compensation expense during the nine months ended September 30, 2016 and 2015, respectively.

*Research and Development*

Research and development expenses for the nine months ended September 30, 2016 were \$3.9 million compared to \$2.5 million for the nine months ended September 30, 2015. The \$1.4 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. Research and development expenses included \$0.2 million in share-based compensation expense during the nine months ended September 30, 2016. There was no share-based compensation expense during the nine months ended September 30, 2015.

*Acquired In-process Research and Development*

No acquired in-process research and development expenses were incurred during the nine months ended September 30, 2016. Acquired in-process research and development expenses during the nine months ended September 30, 2015 were \$0.9 million which was the result of an equity milestone payment under our license agreement with Pfizer. We issued 675,250 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) Income*

Interest (expense) income for the nine months ended September 30, 2016 was \$0.1 million compared to \$(0.9) million for the nine months ended September 30, 2015. The \$1.0 million increase in net interest income, primarily non-cash, was largely due to the amortization of the note premium associated with the July 2015 Interim Notes, fair value adjustments of the derivative liability associated with the Interim Notes, and interest earnings of \$9,000 from IPO cash proceeds.

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Interest income was offset in part by non-cash interest expense associated with the conversion of the April 2016 Interim Notes along with the amortization of the underlying beneficial conversion feature. The unpaid principal and accrued interest on the Convertible Notes converted into shares of Series A preferred stock on March 31, 2015 and no Convertible Notes were outstanding following such date. The principal and accrued and unpaid interest on the Interim Notes converted to common stock immediately prior to the closing of the IPO, and as a result, no Interim Notes were outstanding as of September 30, 2016.

## **Liquidity and Capital Resources**

### ***Capital Resources***

As of September 30, 2016, our principal sources of liquidity consisted of cash and cash equivalents of approximately \$28.4 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;
- 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***

On August 4, 2016, our Registration Statement on Form S-1 (File No 333-210815) relating to our IPO of our common stock was declared effective by the Securities and Exchange Commission. Pursuant to such Registration Statement, on August 10, 2016, we closed our IPO whereby 3,000,000 shares of our common stock were sold at a public offering price of \$10.00 per share. On September 8, 2016, we closed the sale of 27,755 shares of our common stock at the public offering price of \$10.00 per share, representing a partial exercise of the underwriters' over-allotment option, following which, the IPO terminated. We received net proceeds of approximately \$26.2 million after deducting underwriting discounts and commissions of \$2.1 million and other offering expenses of \$2.0 million.

Our primary source of cash prior to the IPO has been proceeds from the issuance of preferred stock and from the issuance of convertible notes and promissory notes. 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.

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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 converted into shares of the Company's Series A preferred stock upon close of the Series A preferred stock financing on March 31, 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. On August 10, 2016, immediately prior to the closing of the IPO, the Company's Series A preferred stock, together with accrued dividends thereon, converted into 827,205 shares of common stock.

In July and December 2015, we entered into convertible note financings in which we issued 8% Interim Notes in an aggregate principal amount of \$5.5 million to various investors. In February and April 2016, we issued additional 8% Interim Notes in an aggregate principal amount of \$5.2 million to various investors. The principal and accrued and unpaid interest on the Interim Notes converted into shares of common stock immediately prior to the closing of the IPO.

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

	For the Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash used in operating activities	\$ (7,420)	\$ (3,177)
Net cash used in investing activities	—	—
Net cash provided by financing activities	32,169	6,211
Net increase in cash	<u>\$ 24,749</u>	<u>\$ 3,034</u>

#### ***Cash Flow from Operating Activities***

For the nine months ended September 30, 2016, cash used in operating activities of \$7.4 million was attributable to a net loss of \$7.4 million coupled with \$0.7 million in non-cash expense adjustments and a net change of \$0.7 million in our net operating assets and liabilities. The non-cash (income) expenses consisted of \$0.8 million of share-based compensation offset by net non-cash interest income of \$(0.1) million related to both the Interim Notes and the premium conversion derivative. The change in operating assets and liabilities was primarily attributable to an increase in our prepaid expenses and accounts payable offset in part by a decrease in accrued liabilities associated with fluctuations in our operating expense payments.

For the nine months ended September 30, 2015, cash used in operating activities of \$3.2 million was attributable to a net loss of \$6.5 million, partially offset by \$2.0 million in non-cash expenses and a net change of \$1.3 million in our net operating assets and liabilities. The non-cash expenses consist of \$0.2 million of share-based compensation, non-cash interest of \$0.9 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 nine months ended September 30, 2016 was \$32.2 million consisting of \$30.3 million in proceeds, net of discounts, commissions and other offering costs of \$3.3 million paid through September 30, 2016, and 5.2 million in proceeds from the issuance of Interim Notes in February 2016 and April 2016.

Net cash provided by financing activities during the nine months ended September 30, 2015 was \$6.2 million consisting of \$1.5 million in proceeds from the issuance of Series A preferred stock and \$4.8 million in proceeds from the issuance of convertible notes, offset by financing costs of \$0.1 million associated with the IPO.

**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.

The development of gemcabene is subject to numerous uncertainties, and we have based these estimates on assumptions that may prove to be substantially different than we currently anticipate and 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 that we will ever be profitable or generate positive cash flow from operating activities.

Furthermore, we will need to raise additional capital to continue to fund the further development of gemcabene and other potential product candidates, our operations, and commercialization of gemcabene and other potential product candidates, if approved.

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of September 30, 2016, which represent material expected or contractually committed future obligations.

	Payments Due by Period				Total
	Less than 1 year	1-3 Years	3-5 Years	More than 5 years	
Facility lease	\$ 101	\$ 185	\$ —	\$ —	\$ 286
Total	\$ 101	\$ 185	\$ —	\$ —	\$ 286

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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. The royalty rates range from the high single digits to the low teens depending on the level of net sales. 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 September 30, 2016, 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.

#### **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.

During the nine months ended September 30, 2016, there were no material changes to our critical accounting policies or estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our final prospectus filed pursuant to Rule 424(b) with the SEC on August 8, 2016.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under the rules and regulations of the Securities and Exchange Commission.

## **Recent Accounting Pronouncements**

Refer to note 2 to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recently issued accounting pronouncements.

## **ITEM 3. 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 September 30, 2016, we had cash and cash equivalents of \$28.4 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.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information we are required to disclose in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We designed and evaluate our disclosure controls and procedures recognizing that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance and not absolute assurance of achieving the desired control objectives. Also, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15(d)-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of September 30, 2016. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2016.

### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

The Company may be subject to claims and lawsuits that arise primarily in the ordinary course of business. The Company believes that the disposition or ultimate resolution of any such claims and lawsuits will not have a material adverse effect on the financial position, results of operations or cash flows of the Company.

## ITEM 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by such forward-looking statements as a result of various factors, including those set forth below. 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 the IPO. 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 report 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 three late stage clinical trials by the end of 2016. 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 outcomes trial, we will need substantial additional funds, and we cannot assure you that the results of any such outcomes 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 clinical 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 late stage clinical trials of gemcabene will commence by the end 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 outcomes 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, and 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 outcomes 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 outcomes 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 outcomes 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. Although the validity of lipid-lowering effects (including LDL-C reduction) as a surrogate endpoint for cardiovascular benefit continues to be debated in the medical community, given historical precedent and recent FDA guidance, our current development timeline for gemcabene does not contemplate the completion of a cardiovascular outcomes trial prior to approval. 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:

- 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;

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- 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. We are also exploring the utility of gemcabene for nonalcoholic steatohepatitis (NASH) and/or nonalcoholic fatty liver disease (NAFLD). 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 or other indications, our commercial opportunity will be limited.

We may pursue clinical development of additional product candidates, including product candidates that we acquire or in-license. Acquiring, in-licensing, developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of the IPO 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.

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 triglyceride levels in broader patient populations, including HeFH, ASCVD and SHTG. The Company is also exploring indications in NASH and/or NAFLD. 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 outcomes 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 outcomes 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 outcomes 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 \$7.4 million for the nine months ended September 30, 2016 and \$9.0 million for the year ended December 31, 2015. As of September 30, 2016, we had an accumulated deficit of \$19.8 million. We have financed our operations primarily through the issuance of common stock in our IPO, a private placement of our preferred stock and the issuance of 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, 2015, our independent registered public accounting firm has issued its report on our

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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 the IPO, together with cash on hand, will be sufficient to fund our operations to mid-2018, 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 and making regulatory filings.

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 and 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 reserved under the A&R 2015 Plan is 2,400,000 shares, with 269,522 shares remaining available for issuance following the grant of options to purchase an aggregate of 1,825,200 shares of common stock to certain officers, directors, employees and consultants in connection with the IPO. The number of shares of our common stock reserved for issuance under the A&R 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2017 and continuing through and including January 1, 2026, to an amount equal to 20% of the fully-diluted shares as of December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors.

In September 2016 our board of directors approved the Inducement Plan. We initially reserved 300,000 shares of common stock to be used exclusively for grants of awards to individuals who were not previously our employees or directors, as an inducement material to the individual's entry into employment with us within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. The Inducement Plan was approved by our board of directors without stockholder approval pursuant to Rule 5635(c)(4), and the terms and conditions of the Inducement Plan are substantially similar to our stockholder-approved A&R 2015 Plan.

To the extent these outstanding options are ultimately exercised or the number of shares available for future grant each year are increased, investors will sustain further dilution.

**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 until ongoing preclinical toxicology studies are complete, 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 (FDCA) 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 late stage 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.

There have been judicial and Congressional challenges and amendments to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These new laws have resulted in additional reductions in Medicare and other healthcare funding and otherwise may 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. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. 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 current and 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;

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- 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

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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, Livalo marketed by Kowa Pharmaceuticals America, Inc. (Kowa), Zocor marketed by Merck & Co., Inc. (Merck), Lipitor marketed by Pfizer, and their generic versions;
- cholesterol absorption inhibitors, such as Zetia, marketed by Merck;
- 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;
- other lipid-lowering monotherapies, including: fibrates, such as TriCor and Trilipix, both marketed by AbbVie Inc. (AbbVie), and Lipofen marketed by Kowa; niacin, such as Niaspan marketed by AbbVie; 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; 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, RGEN-1500 being developed by Regeneron Pharmaceuticals, Inc. and MBX-8025 developed by CymaBay Therapeutics, Inc.;
  - for HeFH and ASCVD, drugs include: oral cholesteryl ester transfer protein inhibitors, such as anacetrapib being developed by Merck and TA-8995 being developed by Amgen/Dezima; ATP citrate lyase inhibitor, ETC-1002 developed by current Esperion; and PCSK9 inhibitors, such as ALN-PCSsc 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 Ionis Pharmaceuticals, Inc. (formerly 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;

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- 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;

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- 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 part or all of 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 will need to manufacture 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

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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 May 2, 2016, our patent estate, including patents we own or license from third parties, on a worldwide basis, included four issued U.S. patents and eight pending U.S. patent applications and 23 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 U.S. Patent Number 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 Number 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 Number 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.

In 2015, we filed two new provisional patent applications, one for methods of treatment of mixed dyslipidemia using gemcabene in combination with statins and treatment of NASH using gemcabene as monotherapy (U.S. Provisional Patent Application Number 62/252,195), and the other relating to fixed dose combinations and modified release formulations of gemcabene and statins (U.S. Provisional Patent Application Number 62/252,147), as well as two non-provisional patent applications on methods of large scale manufacturing for making dicarboxyalkyl ethers (US Application Number 14/942,765 and corresponding PCT application Number PCT/US2015/060917). The two provisional applications, if issued, are expected to expire in 2036. The two non-provisional applications, if issued, are expected to expire in 2035. As of May 2, 2016, we filed four new provisional patent applications: U.S. Provisional Patent Application Numbers 62/295,292, 62/300,393, 63/30,0415 and 62/314,597.

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;

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- 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 NCE 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 NCE 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 FDC Act, as amended, a NCE 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, NCEs 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 NCE 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 NCE 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.***

In 2011, the United States enacted wide-ranging patent reform legislation with the America Invents Act (AIA).

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 Corporation 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 our executive officers, 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 September 30, 2016, we had ten 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 plan to conduct clinical trials outside of the United States. We are subject to numerous risks associated with international business activities, including:

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- 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**

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

The trading price of our common stock following the IPO 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 report, 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;

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- 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 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 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;

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- prohibit stockholders from calling special 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.

***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 the IPO there has been no public market for shares of our common stock. Although our common stock has been approved for listing on NASDAQ, an active trading market for our shares may never develop or be sustained. 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. 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.***

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 exercise significant control over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.***

As of September 30, 2016, our officers, directors, five percent or greater stockholders and their respective affiliates will have beneficial ownership, in the aggregate, of approximately 55.0% of our outstanding common stock.

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 the IPO, and these stockholders may have interests, with respect to their common stock, that are different from yours. 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 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 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 the IPO, (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 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 the IPO. 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.

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We are 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.

***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. As of September 30, 2016, we had 9,270,255 shares of common stock outstanding. This included 3,027,755 shares that we sold in the IPO, which, unless purchased by our affiliates, including our directors, officers, employees, certain existing stockholders and their affiliated entities and other individuals associated with us and members of their respective families in the IPO, may be resold in the public market immediately without restriction. The remaining 6,242,500 shares, as well as any shares purchased by our affiliates in the IPO, are currently or will be restricted as a result of securities laws or lock-up agreements.

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Moreover, holders of an aggregate of approximately 2,124,880 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.

An aggregate of 2,850,000 shares of our common stock are reserved for future issuance under our equity incentive and employee stock purchase plans, 269,522 shares remain available for issuance under the A&R 2015 Plan following the grant of options to purchase an aggregate of 1,825,200 shares of common stock to our officers, directors, employees and consultants in connection with the IPO, and all 300,000 shares reserved the Inducement Plan and 150,000 shares reserved under our employee stock purchase plan remained available for issuance as of September 30, 2016. Such shares 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.

***Our issuance of the common stock in connection with the IPO may have resulted in an “ownership change” at the time of issuance, or has increased 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 September 30, 2016, we had approximately \$5.5 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 \$372,000 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 have experienced or if we experience in the future 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 have experienced an ownership change as a result of our issuance of common stock in connection with the IPO. 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 having resulted 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 was no ownership change as a result of such issuance, the issuance of stock pursuant to the IPO will be taken into account in determining the cumulative change in our ownership for Section 382 purposes. As a result, the IPO has materially increased 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 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 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

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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.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**USE OF PROCEEDS**

*(a) Sales of Unregistered Securities*

None

*(b) Use of Proceeds from Public Offering of Common Stock*

On August 4, 2016, our Registration Statement on Form S-1 (File No 333-210815) relating to our IPO was declared effective by the SEC. The Registration Statement registered an aggregate of 3,450,000 shares of our common stock, including 450,000 shares of common stock registered to cover in full over-allotments by the underwriters. On August 10, 2016, we closed our IPO whereby 3,000,000 shares of our common stock were sold at a public offering price of \$10.00 per share. On September 8, 2016, we closed the sale of 27,755 shares of our common stock at the public offering price of \$10.00 per share, representing a partial exercise of the underwriters' over-allotment option, following which, the IPO terminated.

The managing underwriters of the IPO were Jefferies LLC and RBC Capital Markets, LLC. We paid to the underwriters of the initial public offering underwriting discounts and commissions totaling approximately \$2.1 million. In addition, we incurred expenses of approximately \$2.0 million which, when added to the underwriting discounts and commissions, amounted to total expenses of approximately \$4.1 million. Thus, the net offering proceeds, after deducting underwriting discounts and commissions and offering expenses, were approximately \$26.2 million.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on August 8, 2016.

*(c) Stock Repurchases*

None.

**ITEM 3. DEFAULT UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not Applicable.

**ITEM 6. EXHIBITS**

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF DOCUMENT</b>
3.1	Third Amended and Restated Certificate of Incorporation of Gemphire Therapeutics Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on August 10, 2016).
3.2	Amended and Restated Bylaws of Gemphire Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on August 10, 2016).
10.1*	Form of Amended and Restated 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-210815, filed on June 13, 2016).
10.2*	Form of 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-210815, filed on June 13, 2016).
10.3*	Employment Agreement by and between the Registrant and Mina Sooch (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, File No. 333-210815, filed on April 18, 2016).
10.4*	Employment Agreement by and between the Registrant and Jeffrey S. Mathiesen (incorporated by reference to Exhibit 10.6 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-210815, filed on June 13, 2016).
10.5*	Employment Agreement by and between the Registrant and Charles L. Bisgaier (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, File No. 333-210815, filed on April 18, 2016).
10.6*	Form of Executive Officer Employment Agreement (incorporated by reference to Exhibit 10.8 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-210815, filed on June 13, 2016).
10.7	Lease Agreement, dated as of May 18, 2016 and commencing on August 1, 2016, by and between the Registrant and North Laurel Project, LLC (incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-210815, filed on June 13, 2016).
10.8*	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.15 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-210815, filed on June 13, 2016).

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31.1	Certification of Principal Executive Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of The Sarbanes Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of The Sarbanes Oxley Act of 2002
32.1	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
*	Indicates management contract or compensatory plan.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Registrant: Gemphire Therapeutics Inc.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ MINA SOOCH</u> Mina Sooch	President and Chief Executive Officer (Principal Executive Officer)	November 2, 2016
<u>/s/ JEFFREY S. MATHIESEN</u> Jeffrey S. Mathiesen	Chief Financial Officer (Principal Financial and Accounting Officer)	November 2, 2016

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101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\* Indicates management contract or compensatory plan.

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, Mina Sooch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gemphire Therapeutics Inc. for the quarterly period ended September 30, 2016;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [Intentionally Omitted];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2016

/s/ MINA SOOCH

Name: Mina Sooch

Title: President and Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, Jeffrey S. Mathiesen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gemphire Therapeutics Inc. for the quarterly period ended September 30, 2016;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Intentionally Omitted];
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2016

/s/ JEFFREY S. MATHIESEN

Name: Jeffrey S. Mathiesen

Title: Chief Financial Officer

(Principal Financial Officer)

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER,  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002\***

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, Mina Sooch, President and Chief Executive Officer of Gemphire Therapeutics Inc. (the "Company"), and Jeffrey S. Mathiesen, Chief Financial Officer of the Company, each hereby certify that, to the best of their knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2016, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and results of operations of the Company for the period covered by the Quarterly Report.

/s/ MINA SOOCH  
President and Chief Executive Officer

/s/ JEFFREY S. MATHIESEN  
Chief Financial Officer

Dated: November 2, 2016

Dated: November 2, 2016

- This certification accompanies the report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Gemphire Therapeutics Inc. under the Securities Act of 1933, as amended, or the Exchange Act made before or after the date of the report, irrespective of any general incorporation language contained in such filing.
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