# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

Form 10-Q

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$\times$	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 1	.5(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the Quarterly Period Ended June 30, 2018	
	O	R
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 1	15(d) OF SECURITIES EXCHANGE ACT OF 1934
	For the transition period from to	
	Commission file n	umber 001-37809
	<b>Gemphire The</b> (Exact name of Registrant	
(5	<b>Delaware</b> State or other jurisdiction of incorporation or organization)	47-2389984 (IRS Employer Identification No.)
	17199 N. Laurel Park Drive, Suite 401, Livonia, MI	48152
	(Address of principal executive offices) (734) 24	
	(Registrant's telephòne nur	
	<b>Not App</b> (Former name, former address and former	oficable fiscal year, if changed since last report)
of 1934	e by check mark whether the registrant (1) has filed all reports red during the preceding 12 months (or for such shorter period that the filing requirements for the past 90 days. Yes $\boxtimes$ No $\square$	quired to be filed by Section 13 or 15(d) of the Securities Exchange Act he registrant was required to file such reports), and (2) has been subject
File rec	e by check mark whether the registrant has submitted electronica quired to be submitted and posted pursuant to Rule 405 of Regula h shorter period that the registrant was required to submit and pos	lly and posted on its corporate Web site, if any, every Interactive Data tion S-T ( $\S 232.405$ of this chapter) during the preceding 12 months (or such files). Yes $\boxtimes$ No $\square$
compar	e by check mark whether the registrant is a large accelerated by, or an emerging growth company. See the definitions of "large ing growth company" in Rule 12b-2 of the Exchange Act.	filer, an accelerated filer, a non-accelerated filer, a smaller reporting accelerated filer," "accelerated filer," "smaller reporting company" and
	Large accelerated filer $\Box$	Accelerated filer $\square$
	Non-accelerated filer $\square$ (Do not check if a smaller reporting company)	Smaller reporting company $\ oxtimes$
	Emerging growth company $\ oxtimes$	
f an ei with an	merging growth company, indicate by check mark if the registra y new or revised financial accounting standards provided pursuan	nt has elected not to use the extended transition period for complying t to Section 13(a) of the Exchange Act. $\boxtimes$
Indicate	e by check mark whether the registrant is a shell company (as defi	ned in Rule 12(b)-2 of the Exchange Act). Yes □ No ⊠
Γhe nu	mber of outstanding shares of the registrant's common stock, \$0.0	01 par value, as of August 7, 2018 was 14,265,411.

# Gemphire Therapeutics Inc. FORM 10-Q INDEX

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# PART I – FINANCIAL INFORMATION ITEM 1 – FINANCIAL STATEMENTS

# Gemphire Therapeutics Inc. Condensed Balance Sheets (in thousands, except share amounts and par value)

		June 30, 2018 (maudited)	Dec	ember 31, 2017
Assets	,	ŕ		
Current assets:				
Cash and cash equivalents	\$	28,039	\$	18,473
Prepaid expenses		719		490
Deferred offering costs		_		21
Other assets		40		25
Total current assets		28,798		19,009
Deposits		8		8
Total assets	\$	28,806	\$	19,017
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	2,569	\$	4,025
Accrued liabilities		994		1,010
Term loan - current portion		2,652		1,355
Total current liabilities		6,215		6,390
Long-term liabilities:				
Term loan		7,540		8,683
Other liabilities		3		3
Total liabilities		13,758		15,076
Commitments and contingencies (Note 5)				
Stockholders' equity:				
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of June 30, 2018 and December 31, 2017, no shares issued or outstanding as of June 30, 2018 and December 31, 2017.		_		_
Common stock, \$0.001 par value; 100,000,000 shares authorized as of June 30, 2018 and December 31, 2017, 14,232,313 and 10,633,042 shares issued and outstanding at June 30,		22		10
2018 and December 31, 2017, respectively.		22		18
Additional paid–in capital  Accumulated deficit		89,402		64,397
	_	(74,376)	_	(60,474)
Total stockholders' equity	ф.	15,048	ф.	3,941
Total liabilities and stockholders' equity	\$	28,806	\$	19,017

# Gemphire Therapeutics Inc. Condensed Statements of Comprehensive Loss (in thousands, except share and per share amounts) (unaudited)

	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2018		2017	2018			2017	
Operating expenses:								
General and administrative	\$ 2,574	\$	4,678	\$	4,661	\$	6,901	
Research and development	3,960		5,837		8,937		11,117	
Total operating expenses	 6,534		10,515		13,598		18,018	
Loss from operations	 (6,534)		(10,515)		(13,598)		(18,018)	
Interest (expense) income	(144)		13		(304)		25	
Other expense	` —		_		` —		(5)	
Loss before income taxes	(6,678)		(10,502)		(13,902)		(17,998)	
Provision (benefit) for income taxes	`		`		`		`	
Net loss	(6,678)		(10,502)		(13,902)		(17,998)	
Other comprehensive loss, net of tax								
Comprehensive loss	\$ (6,678)	\$	(10,502)	\$	(13,902)	\$	(17,998)	
Net loss per share:	<u> </u>							
Basic and diluted (Note 9)	\$ (0.47)	\$	(0.99)	\$	(1.04)	\$	(1.79)	
Number of shares used in per share calculations:								
Basic and diluted	14,232,313		10,603,371		13,340,941		10,065,287	

# Gemphire Therapeutics Inc. Condensed Statements of Changes in Stockholders' Equity (in thousands, except share amounts) (unaudited)

	Preferr Shares	 tock tount	Common Stock Additional Paid–In Capital							
Balance at January 1, 2017	_	\$ _	9,270,255	\$	17	\$ 47,674	\$	(27,059)	\$	20,632
Issuance of common stock from private placement	_	—	1,324,256		1	8,978				8,979
Issuance of detachable stock warrants in										
connection with private placement	_	_	_		_	3,562		_		3,562
Issuance costs of private placement	_	—	_		_	(1,257)		_		(1,257)
Exercise of stock options	_	—	12,850		—	13		_		13
Share–based compensation — employee	_	—	_		_	3,784		_		3,784
Share–based compensation — non–employee	_	—	_		—	15		_		15
Net loss		—						(17,998)		(17,998)
Balance at June 30, 2017		\$ _	10,607,361	\$	18	\$ 62,769	\$	(45,057)	\$	17,730
Balance at January 1, 2018	_	\$ —	10,633,042	\$	18	\$ 64,397	\$	(60,474)	\$	3,941
Issuance of common stock	_	—	3,592,858		4	25,146		_		25,150
Issuance costs	_	_	_		_	(2,093)		_		(2,093)
Exercise of stock options	_	_	6,413		_	23		_		23
Share–based compensation — employee	_	_	_		_	1,927		_		1,927
Share—based compensation — non-employee	_	_	_		_	2		_		2
Net loss								(13,902)		(13,902)
Balance at June 30, 2018		\$	14,232,313	\$	22	\$ 89,402	\$	(74,376)	\$	15,048

# Gemphire Therapeutics Inc. Condensed Statements of Cash Flows (in thousands) (unaudited)

	For the Six Months Ended June 30,		
	2018		2017
Operating activities			
Net loss	\$ (13,902)	\$	(17,998)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	1,929		3,799
Non-cash discount amortization on term loan	154		_
Change in assets and liabilities:			
Prepaid expenses and other assets	(223)		208
Accounts payable	(1,456)		1,456
Accrued and other liabilities	 (16)		(307)
Net cash used in operating activities	(13,514)		(12,842)
Investing activities			
Net cash provided by (used in) investing activities	 		
Financing activities			
Exercise of stock options	23		13
Proceeds from sale of common stock	25,150		12,541
Offering costs	 (2,093)		(1,254)
Net cash provided by financing activities	 23,080		11,300
Net increase (decrease) in cash and cash equivalents	9,566		(1,542)
Cash and cash equivalents at beginning of period	 18,473		24,033
Cash and cash equivalents at end of period	\$ 28,039	\$	22,491
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	\$ 	\$	
Cash paid for interest	\$ 232	\$	
Supplemental non-cash financing transactions:	 		
Offering costs in accounts payable and accrued liabilities	\$ 	\$	3

# 1. The Company and Basis of Presentation

The Company, headquartered in Livonia Michigan, is a clinical-stage biopharmaceutical entity 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 to date have been conducting research and development activities, planning and conducting 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, if approved; expand its management scientific staff; finance its operations; and find collaboration partners to further advance development and commercial efforts.

#### **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 \$26.1 million after deducting underwriting discounts and commissions of \$2.1 million and other offering expenses of \$2.1 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.

# **Private Placement Offering**

On March 10, 2017, the Company entered into a securities purchase agreement for a private placement (the Private Placement) with a select group of accredited investors whereby, on March 15, 2017 the Company issued and sold 1,324,256 units at a price of \$9.47 per unit for gross proceeds of approximately \$12.5 million. Each unit consists of one share of the Company's common stock and a warrant to purchase 0.75 shares of common stock. The warrants have an exercise price of \$10.40 per share and are exercisable for a period of five years from the date of issuance. On April 20, 2017, the registration statement on Form S-1 (File No 333-217296) for the resale of the shares of common stock issued in the Private Placement and the shares of common stock to be issued upon exercise of the warrants issued in the Private Placement was declared effective by the SEC, and on September 1, 2017, the Company filed a post-effective amendment to convert the registration statement into Form S-3 for the registration of any unsold Private Placement shares, which included an updated prospectus relating to such unsold shares.

# **Follow-On Public Offering**

On February 12, 2018, the Company completed an underwritten public offering (the Follow-On Offering) of 3,142,858 shares of common stock at the public offering price of \$7.00 per share. As part of such offering, the Company issued 450,000 additional shares of common stock representing partial exercise of the underwriters' overallotment option. The

Company received net proceeds of approximately \$23.1 million after deducting underwriting discounts and commissions and offering expenses.

# **Capital Requirements**

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 Company's operations with equity and/or debt issuances. The Company's management believes the Company's cash and cash equivalents on hand, are adequate to fund the Company's operations for at least the next 12 months. 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.

#### **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 annual 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 condensed financial statements 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, 2017 included in the Company's Annual Report on Form 10-K filed with the SEC on March 20, 2018. The condensed balance sheet at December 31, 2017 was derived from the audited financial statements.

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.

#### 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. The Company invests excess cash in readily available checking and savings accounts and invests in highly liquid investments in money market accounts.

# **Fair Value of Financial Instruments**

The Company's condensed financial instruments include principally cash and cash equivalents, other 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 10 — 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 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.

#### 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.

# **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. The Company records 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).

#### **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.

# **Recently Adopted Accounting Pronouncements**

In November 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-18. *Statement of Cash Flows (Topic 230): Restricted Cash.* The objective of this ASU is to eliminate the diversity in practice related to the classification of restricted cash or restricted cash equivalents in the statement of cash flows. 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. The Company adopted this standard on January 1, 2018 and it did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting* (ASU 2016-09), which provides guidance about which changes to the terms or conditions of a share-based payment awards require an entity to apply modification accounting in Topic 718. This pronouncement is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has adopted this standard on January 1, 2018 and it did not have a material impact on the Company's financial statements.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740)*, that codified the SEC Staff Accounting Bulletin 118 (SAB 118) issued on December 22, 2017, which provides guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (the TCJA). SAB 118 provides a measurement period that should not extend beyond one year from the enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the TCJA for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the TCJA is incomplete, but for which they are able to determine a reasonable estimate, it must record a provisional amount in the financial statements. Provisional treatment is proper in light of anticipated additional guidance from various taxing authorities, the SEC, the FASB, and even the Joint Committee on Taxation. If a company cannot determine a provisional amount to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the TCJA. The Company has applied this guidance to its financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes the revenue recognition requirements in FASB ASC 605. The new guidance primarily states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In January 2017 and September 2017, the FASB issued several amendments to ASU 2014-09, including updates stemming from SEC Accounting Staff Announcement in July 2017. The amendments and updates included clarification on accounting for principal versus agent considerations (i.e., reporting gross versus net), licenses of intellectual property and identification of performance obligations. These amendments and updates do not change the core principle of the standard but provide clarity and implementation guidance. The Company has adopted this standard on January 1, 2018 and selected the modified retrospective transition method. The Company modified its accounting policies to reflect the requirements of this standard; however, the planned adoption will not affect the Company's financial statements and related disclosures for these periods or future periods until the Company generates revenues.

#### **Recent Accounting Pronouncements Not Yet Adopted**

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)* and subsequently amended the guidance relating largely to transition considerations under the standard in January 2017 and July 2018. 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.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share*, *Distinguishing Liabilities from Equity and Derivatives and Hedging*, which changes the accounting and earnings per share for certain instruments with down round features. The amendments in this ASU should be applied using a cumulative-effect adjustment as of the beginning of the fiscal year or retrospective adjustment to each period presented and is effective for annual periods beginning after December 15, 2018, and interim periods within those periods. The Company is currently evaluating the requirements of this new guidance and has not yet determined its impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718)*: Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should generally apply the requirements of Topic 718 to nonemployee awards except in circumstances where there is specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The guidance also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. This guidance is effective for annual reporting periods beginning after December 15, 2018, with early adoption permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the impact of the new guidance on its financial statements.

# 3. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	Ju	June 30,		ember 31,
		2018		2017
Accrued compensation and other payroll liabilities	\$	549	\$	306
Legal costs		124		91
Accrued interest		41		38
Other research and development expenses		234		522
Other general and administrative expenses		46		53
Total	\$	994	\$	1,010

# 4. Debt

# Term Loan

On July 24, 2017, the Company entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB) for a term loan of up to \$15.0 million (the Term Loan), subject to funding in several tranches. The Loan Agreement was amended on July 31, 2018 (see Note 14 – *Subsequent Events*). This note describes the terms of the Loan Agreement as in effect on June 30, 2018.

The Company drew the initial tranche of \$10.0 million on July 24, 2017. An additional tranche of \$5.0 million may have been available to be drawn by the Company through July 31, 2018 conditioned on the occurrence of certain clinical and preclinical milestones. The Company was in compliance with the Loan Agreement covenants as of June 30, 2018.

All amounts advanced under the Term Loan mature on February 1, 2021 and have an interest-only monthly payment period through August 1, 2018; the interest-only period may be extended to February 1, 2019 conditioned on the occurrence of certain clinical and pre-clinical milestones. Following the interest-only payment period, the Company must begin making monthly payments of principal and interest until the maturity date. Interest will accrue on the unpaid principal balance at a floating per annum rate equal to the prime rate, except that, following an event of default, interest

will accrue at a rate up to 5% above the rate that is otherwise applicable. The prime rate in effect for the six month period ending June 30, 2018 ranged from 4.5% to 5.00%. Lastly, debt issue costs in the amount of \$0.1 million were incurred as of June 30, 2018 and December 31, 2017. The debt issue costs were recorded as a discount to the Term Loan and are being amortized ratably to interest expense over the term of the loan.

The Loan Agreement requires the Company to pay the following fees: (i) upon the maturity, acceleration or prepayment of the Term Loan, a final payment fee of 10% of the funded principal amount of the Term Loan which was recorded as a liability upon issue and then discounted to be subsequently amortized ratably to interest expense over the term of the loan, (ii) a success fee of 3.5% of the funded principal amount of the Term Loan in the event any of the following occur prior to 5:00 pm Eastern Time on July 24, 2024: (a) the Company receives FDA approval for any new drug application for gemcabene, (b) a sale or other transfer of all or substantially all of the assets of the Company occurs, (c) a merger or consolidation of the Company with or into another person or entity occurs where the holders of the Company's outstanding voting equity securities immediately prior to such merger or consolidation hold less than a majority of the issued and outstanding voting equity securities of the successor immediately following such transaction or (d) any sale by the holders of the Company's outstanding voting equity securities where such holders do not continue to hold at least a majority of the Company's issued and outstanding voting equity securities, and (iii) upon termination of the Loan Agreement prior to the maturity date for any reason, a prepayment fee equal to 2% (if such prepayment occurs prior to the first anniversary) or 1% (if such prepayment occurs thereafter) of the funded principal amount of the Term Loan.

In the event a positive clinical trial event as defined in the Loan Agreement did not occur by March 31, 2018, on such date, the Company would have been required to (i) provide cash security and maintain a cash balance in a restricted account at SVB in an amount of at least 50% of the amounts the Company owes to SVB or (ii) prepay the Term Loan in its entirety. On November 10, 2017, the Company provided SVB evidence of a positive clinical trial event. In the event a pre-clinical event as defined by the Loan Agreement does not occur by July 31, 2018, on such date, the Company must either (i) provide cash security and maintain a cash balance in a restricted account at SVB in an amount of at least 100% of the amounts the Company owes to SVB or (ii) prepay the Term Loan in its entirety. In each case, if the Company chooses to prepay the Term Loan, in addition to the repayment of the outstanding principal and accrued and unpaid interest, the Company is required to pay the final payment fee and, if applicable, the success fee, but not the prepayment fee. A pre-clinical event had not occurred as of July 31, 2018 and, on such date, the Company and SVB amended the Loan Agreement (see Note 14 – *Subsequent Events*).

The Company recorded \$0.2 million and \$0.4 million in interest expense related to the Term Loan for the three and six month periods ending June 30, 2018, respectively. The Term Loan was not outstanding during the comparable periods in 2017.

As of June 30, 2018, the minimum aggregate future payments under the Term Loan are as follows (in thousands):

	 June 30,
2018	\$ 992
2019	4,791
2020	4,567
2021	1,370
Total minimum payments	11,720
Amount representing interest and discounts	 (1,528)
Present value of minimum payments	10,192
Current portion	 (2,652)
Long-term portion	\$ 7,540

Future minimum interest payments under the Term Loan are assumed at a 5.00% per annum rate.

See Note 14 – *Subsequent Events* for a description of the amendment to the Loan Agreement entered into on July 31, 2018.

# 5. Commitments and Contingencies

# Pfizer License Agreement

In April 2011, the Company and Pfizer Inc. (Pfizer) entered into an exclusive license agreement for the clinical product candidate gemcabene, which was subsequently amended and restated in August 2018 (as so amended, the Pfizer Agreement) (See Note 14 — *Subsequent Events*). In exchange for this worldwide exclusive license to certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene, the Company agreed to certain milestone and royalty payments on future sales (See Note 6 — *License Agreement*). As of June 30, 2018, 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 Pfizer Agreement, and as such, no liabilities were recorded related to the Pfizer Agreement.

#### **Other Agreements**

In May 2016, the Company entered into a non-cancellable lease agreement for its headquarters location, commencing in the third quarter of 2016. The initial term of the agreement is 3 years with an initial monthly base rent of approximately \$8,400 and increasing to approximately \$8,900 during the last year of the lease term. In conjunction with entering into the new lease agreement, 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 expired in September 2017 that had nominal rent. The total rent expense was \$26,000 during the three month periods ended June 30, 2018 and 2017, and \$52,000 during the six month periods ended June 30, 2018 and 2017.

Future minimum lease payments under the fixed non-cancellable operating lease through the August 2019 expiration date consist of the following (in thousands):

2018 2019	<u>J</u>	June 30,		
2018	\$	53		
2019		71		
Total	\$	124		

# **Other Commitments and Contingencies**

In the ordinary course of business, from time to time, the Company may be subject to a broad range of claims and legal proceedings that relate to contractual allegations, patent infringement, employment-related matters and other claims. The Company establishes accruals for matters which it believes that losses are probable and can be reasonably estimated. Although it is not possible to predict with certainty the outcome of these matters, the Company is of the opinion that the ultimate resolution of these matters will not have a material adverse effect on its results of operations or financial position.

#### 6. License Agreement

The Company is party to the Pfizer Agreement, as amended in August 2018 (see Note 14 – *Subsequent Events*), for a worldwide exclusive license to certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Pfizer retains the right to make, use and import gemcabene solely for internal research purposes.

In partial exchange for the rights granted by Pfizer, 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 new drug application (or its foreign equivalent) 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. 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 the later of: (a) five (5) years after the first commercial sale in such country; (b) the expiration of all regulatory or data exclusivity for gemcabene in such country; and (c) the expiration or abandonment of the last valid claim of the licensed patents, including any patent term extensions or supplemental protection certificates in such country (collectively, the Royalty Term). 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 June 30, 2018.

The Pfizer Agreement will expire upon expiration of the last Royalty Term. On expiration (but not earlier termination), the Company will have a perpetual, exclusive, fully paid-up, royalty-free license under the licensed patent rights and related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Either party may terminate the Pfizer Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the Pfizer Agreement in the event that (i) the Company or any of its affiliates or sublicenses contests or challenges, or supports or assists 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 the Pfizer Agreement or (ii) the Company or any of its affiliates or sublicensees fails to achieve the first commercial sale in at least one country by April 16, 2024. Furthermore, upon termination of the Pfizer Agreement by Pfizer for any of the foregoing reasons, the Company grants Pfizer a non-exclusive, fully paid-up, royalty free, worldwide, transferrable, perpetual and irrevocable license to use any intellectual property rights arising from the development or commercialization of gemcabene by the Company and any trademarks identifying gemcabene and agrees to transfer regulatory filings and approvals for gemcabene. The Company may terminate the License Agreement for convenience upon 90 days' written notice and payment of an early termination fee.

#### 7. Stockholders' Equity

#### Common Stock

The Company had 14,232,313 and 10,633,042 shares of its common stock issued and outstanding as of June 30, 2018 and December 31, 2017, 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.

In the first quarter of 2018, the Company completed the Follow-On Offering of 3,592,858 shares of common stock which includes 450,000 shares of common stock purchased by the underwriters upon the partial exercise of their overallotment option, at the public offering price of \$7.00 per share. The Company received net proceeds of approximately \$23.1 million after deducting underwriting discounts and commissions and offering expenses. The costs incurred related to the Follow-On Offering were \$2.1 million through June 30, 2018.

On March 15, 2017, the Company issued and sold 1,324,256 units at a price of \$9.47 per unit for gross proceeds of approximately \$12.5 million in connection with the Private Placement. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.75 shares of common stock. The Company received net proceeds of approximately \$11.2 million after deducting underwriting discounts and commissions and offering expenses. Offering costs incurred related to the 2017 Private Placement were \$1.3 million through June 30, 2018 and December 31, 2017.

#### Warrants

In connection with the Private Placement, the Company issued warrants to the investors participating in the financing to purchase an additional 993,204 shares of common stock. The warrants have a term of five years and were exercisable immediately upon issuance with an exercise price equal to \$10.40 per share. The warrants were classified as additional paid-in capital and recorded based on their relative fair value to the underlying common shares issued in the Private Placement. The fair market value of the warrants was approximately \$4.9 million. The warrants were valued using the Black-Scholes method with the following assumptions: a risk-free interest rate of 2.0%. a contractual term of five years, zero dividend yield and a volatility factor of 65.1%. During the three and six month periods ending June 30, 2018 and 2017, no warrant shares were exercised. As of June 30, 2018, warrants to purchase 978,204 shares of common stock were outstanding.

# **Dividend Rights**

Common stock holders are entitled to receive dividends at the sole discretion of the board of directors of the Company. There have been no dividends declared on common stock as of June 30, 2018. Furthermore, the Loan Agreement contains covenants prohibiting the Company from, among other things, paying dividends or distributions.

# **Voting Rights**

The holders of common stock are entitled to one vote for each share of common stock along with all other classes and series of stock of the Company on all actions to be taken by the stockholders of the Company, including actions that would amend the certificate of incorporation of the Company to increase the number of authorized shares of the common stock.

# Liquidation Rights

In the event of any liquidation, dissolution, or winding-up of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution post preferential distributions made to preferred stockholders, if any.

#### 8. Share-Based Compensation

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

		Three Months Ended June 30,			Six Mon Jun	ths Ene	ded
	- 2	2018		2017	2018		2017
General and administrative	\$	436	\$	2,684	\$ 1,147	\$	3,253
Research and development		473		279	782		546
Total share-based compensation	\$	909	\$	2,963	\$ 1,929	\$	3,799

#### Restricted Stock Awards

During the three and six months ended June 30, 2018 and 2017, the Company did not grant any restricted stock awards (RSAs). The RSAs previously granted were subject to various vesting schedules and generally vested ratably over a six to 24 month period coinciding with their respective service periods. During the three and six months ended June 30, 2018, no RSAs vested. During the three and six months ended June 30, 2017, zero and 4,009 RSAs vested, respectively. No RSAs were forfeited during the three and six month periods ended June 30, 2018 or 2017.

#### **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.

# Amended and Restated 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.

Under the A&R 2015 Plan, the number of shares of common stock reserved for issuance thereunder automatically increases on January 1st of each year, for a period of 10 years commencing on January 1, 2017 and ending on (and including) January 1, 2026, to an amount equal to 20% of the Company's fully-diluted shares as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Company's board of directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the shares reserved for such year, or that the increase in shares reserved for such year will be less than would have otherwise been allowed under the provision. Effective January 1, 2018, 415,077 shares were added to the A&R 2015 Plan under the share reserve provision. On April 9, 2018, the Company's board of directors adopted, and on May 22, 2018, the Company's stockholders approved, an amendment to the A&R 2015 Plan to increase the number of shares reserved under the A&R 2015 Plan by 300,000 shares to make such shares available for grant in 2018. As a result, the total share reserve as of June 30, 2018 was 3,115,077 shares.

# 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

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. On April 9, 2018, the Company's board of directors approved an amendment to the Inducement Plan to increase the number of shares reserved under the Inducement Plan by 150,000 shares, bringing the total amount of authorized shares reserved under the Inducement Plan to 450,000 shares.

# 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 June 30, 2018, no shares have been purchased under the ESPP.

During the three months ended June 30, 2018 and 2017, the Company granted an aggregate of 350,000 and 60,000 stock options, respectively, and the Company granted an aggregate of 822,000 and 183,500 stock options during the six months ended June 30, 2018 and 2017, respectively, under the A&R 2015 Plan and the Inducement Plan to its officers, directors, employees and consultants, generally vesting over a four-year period. The weighted average grant date fair value for option shares granted during the three months ended June 30, 2018 and 2017 was \$3.57 and \$5.89 per share, respectively, and \$5.07 and \$6.18 per share during the six month periods ended June 30, 2018 and 2017, respectively.

The Company measures the fair value of stock options to employees, consultants and directors on the date of grant with service-based and performance-based vesting criteria using the Black-Scholes option pricing model and market-based vesting criteria using a Monte Carlo simulation 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. The Company records forfeitures when they occur.

The weighted-average assumptions used in the Black-Scholes option-pricing and Monte Carlo simulation models are as follows:

	Three Montl June 3		Six Months Ended June 30,		
	2018 2017		2018	2017	
Expected stock price volatility	66.0%	66.6%	66.3%	65.6%	
Expected life of options (years)	5.7	5.2	5.8	5.8	
Expected dividend yield	0%	0%	0%	0%	
Risk free interest rate	2.9%	1.8%	2.7%	2.0%	

During the three months ended June 30, 2018 and 2017, 127,062 and 451,672 stock options vested, respectively, and 307,410 and 588,025 stock options vested during the six months ended June 30, 2018 and 2017, respectively. During the

second quarter of 2017, the separation of the Company's former chief executive officer resulted in a significant increase to stock-based compensation expense during this period due to stock option vesting acceleration. The vesting acceleration of the former chief executive officer's stock options amounted to \$2.1 million in share-based compensation costs that included all stock options that would have otherwise vested had the former chief executive officer remained employed by the Company through August 4, 2019. These stock options will remain exercisable until the August 3, 2026 termination date of the underlying award agreement. The remaining 150,000 stock options held by the former chief executive officer that would have otherwise vested after August 4, 2019 will be eligible for vesting only in the event of a change of control occurring prior to August 4, 2019.

During the three months ended June 30, 2018 and 2017, 111,389 and zero stock options were forfeited, respectively. During the six months ended June 30, 2018 and 2017, 114,889 and 3,250 stock options were forfeited, respectively. As of June 30, 2018, 3,164,838 stock options were outstanding, 1,505,030 stock options were vested and 370,295 shares in the aggregate were available for future issuance under the A&R 2015 and Inducement Plans.

Unrecognized share-based compensation cost for stock options issued under the A&R 2015 Plan and the Inducement Plan was \$8.1 million as of June 30, 2018. The non-employee portion of the unrecognized compensation cost was estimated utilizing the Company's fair market value for its common stock as of June 30, 2018. The unrecognized share-based expense is expected to be recognized over a weighted average period of 2.2 years for the stock options. There was no remaining unrecognized stock-based compensation related to the RSAs as of June 30, 2018.

# 9. 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. 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 and warrants are considered common stock equivalents while outstanding for this purpose. Diluted earnings are computed utilizing the treasury method for stock options and warrants. 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 six months ended June 30, 2018 and 2017. The following table sets forth the computation of basic and diluted loss per share for the three and six months ended June 30, 2018 and 2017 (in thousands, except share and per share amounts):

	Three Months Ended			Six Months Ended				
	2018		2017		2018			2017
Numerator:								
Net loss	\$	(6,678)	\$	(10,502)	\$	(13,902)	\$	(17,998)
Denominator:								
Basic and diluted weighted average common								
shares outstanding	1	4,232,313		10,603,371		13,340,941		10,065,287
Basic and diluted net loss per share	\$	(0.47)	\$	(0.99)	\$	(1.04)	\$	(1.79)

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 during the three and six months ended June 30, 2018 and 2017:

	Three Mon	ıths Ended	Six Months Ended		
	2018	2017	2018	2017	
Stock options	3,164,838	2,409,821	3,164,838	2,409,821	
Warrants	978,204	993,204	978,204	993,204	

#### 10. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity specific measurement. Fair value is defined as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." Fair value measurements are defined on a three level hierarchy:

**Level 1 inputs:** Unadjusted quoted prices for identical assets or liabilities in active markets;

**Level 2 inputs:** Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, weather directly or indirectly, for substantially the full term of the asset or liability;

**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 June 30, 2018 and December 31, 2017, 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 Term Loan was based on amortized cost which was deemed to approximate fair value. There were no transfers between fair value hierarchy levels during the three and six months ended June 30, 2018 and 2017.

There were no instruments measured on a recurring fair value basis as of June 30, 2018 and December 31, 2017. In addition, no financial instruments were measured on a non-recurring basis for any of the periods presented.

#### 11. Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act (the TCJA), which significantly modified U.S. corporate income tax law, was signed into law by President Trump. The TCJA contains significant changes to corporate income taxation, including but not limited to the reduction of the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and generally eliminating net operating loss carrybacks, allowing net operating losses to carryforward without expiration, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including changes to the orphan drug tax credit and changes to the deductibility of research and experimental expenditures that will be effective in the future). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain, including to what extent various states will conform to the newly enacted federal tax law.

The Company has recorded the necessary provisional adjustments in the financial statements in accordance with its current understanding of the TCJA and guidance currently available as of this filing and recorded a provisional reduction of \$6.8 million to its gross deferred tax assets in the fourth quarter of 2017, the period in which the legislation was enacted. The provisional reduction was fully offset by an equal reduction in the Company's valuation allowance given the Company's historical net losses, resulting in no net income tax expense being recorded. The Company may adjust these provisional amounts in future periods if its interpretation of the TCJA changes or as additional guidance becomes available. Any subsequent adjustment to these amounts is not expected to have a significant impact due to the valuation allowance.

The effective tax rate for the three and six months ended June 30, 2018 and 2017 was zero percent. As a result of the analysis of all available evidence as of June 30, 2018 and December 31, 2017, the Company recorded a full valuation

allowance on its net deferred tax assets. Consequently, the Company reported no income tax benefit for the three and six month periods ended June 30, 2018 and 2017. 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.

#### 12. Defined Contribution Plan

The Company adopted a 401(k) defined contribution plan on September 5, 2017, effective as of January 1, 2017, for all employees over age 21. Employees can defer up to 100% of their compensation through payroll withholdings into the plan subject to federal law limits. Effective January 1, 2018, the Company began matching contributions on deferrals at 100% of deferrals up to 3% of one's contributions and 50% on deferrals over 3%, but not exceeding 5% of one's contributions in order to satisfy certain non-discrimination tests required by the Internal Revenue Code. Employee contributions and any employer matching contributions made to satisfy certain non-discrimination tests required by the Internal Revenue Code are 100% vested upon contribution. Discretionary employer matches vest over a six-year period beginning on the second anniversary of an employee's date of hire. The amount of matching contributions made during the three and six month period ended June 30, 2018 was \$29,000 and \$54,000, respectively. There were no matching contributions made during the comparable periods in 2017.

# 13. Related Party Transactions

The Company rented an office in Northville, Michigan from an LLC owned by one current and one former officer under short-term agreements during the three and six month periods ended June 30, 2017. The original facility lease, as amended, was cancelled and replaced with a cancellable lease agreement in the third quarter of 2016 for limited use of office space in the same Northville location. The new lease agreement became effective in the third quarter of 2016 and expired in September 2017 with a nominal base rent over its term. There was no rent expense under the related party agreements during the three and six months ended June 30, 2018.

In the first quarter of 2018, in connection with an underwritten public offering of 3,592,858 shares of common stock, the offering included 14,286 shares sold to 1 officer, for aggregate proceeds totaling approximately \$0.1 million and 71,429 shares sold to 1 investor who is an affiliate of 1 officer and board member, for proceeds totaling approximately \$0.5 million.

The Private Placement in 2017 included 56,678 units sold to three board members, for aggregate proceeds totaling approximately \$0.5 million, and 52,798 units sold to one investor who was related to one board member, for proceeds totaling approximately \$0.5 million.

#### 14. Subsequent Events

#### Amendment to Term Loan

On July 31, 2018 (the "First Amendment Effective Date"), the Company and SVB entered into a First Amendment (the "Loan Amendment") to the Loan and Security Agreement (the "Original Loan Agreement") with SVB dated July 24, 2017 (the "Initial Effective Date").

As amended by the Loan Amendment, Tranche C is now available through November 30, 2018 conditioned upon, in addition to the occurrence of a Positive Clinical Trial Event (evidence of which was provided to SVB on November 10, 2017) and a Pre-Clinical Event, the occurrence of a Positive Phase 2 NASH Event. "Positive Phase 2 NASH Event" means public disclosure by the Company of evidence satisfactory to SVB, in its sole but reasonable discretion, that the Company has received positive Phase 2 interim data on either its adult familial partial lipodystrophy proof-of-concept clinical trial or its pediatric NAFLD proof-of-concept clinical trial.

Additionally, the provision requiring cash security or prepayment if a Pre-Clinical Event did not occur on or prior to July 31, 2018 was amended to provide that such cash security or prepayment, as described above, is required if a Pre-Clinical

Event does not occur on or prior to September 30, 2019 or, if at any time prior to a Pre-Clinical Event, the Company's unrestricted cash balance at SVB is less than \$18 million.

In the Loan Amendment, (i) the interest-only monthly payment period now ends November 1, 2018 subject to extension to February 1, 2019 upon the occurrence of both a Positive Clinical Trial Event and a Pre-Clinical Event and (ii) the definition of "Prepayment Fee" was revised so that the Prepayment Fee shall equal 2% (if such prepayment occurs prior to the first anniversary of the First Amendment Effective Date, rather than the first anniversary of the Initial Effective Date) or 1% (if such prepayment occurs thereafter) of the funded principal amount of the Term Loan.

In connection with the Loan Amendment, on the First Amendment Effective Date, the Company issued a warrant to SVB (the "Warrant") to purchase 36,000 shares of the Company's common stock at an exercise price of \$7.47 per share. The Warrant is immediately exercisable and has a term of ten years. The exercise price and number and type of shares underlying the Warrant are subject to adjustment upon specified events, including any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. The Warrant contains a "cashless exercise" feature that allows SVB to exercise the Warrant without a cash payment to the Company, on a net issuance basis, based upon the fair market value of the Company's common stock at the time of exercise, upon the terms set forth therein.

# Amendment to Pfizer License Agreement

The Company and Pfizer entered into an agreement on August 2, 2018 that amended and restated in full the Company's license agreement with Pfizer dated April 16, 2011. The following describes the terms of the Pfizer Agreement, as so amended.

The amended and restated Pfizer Agreement contains a number of changes to the original license agreement, including extending the date of the agreed deadline for the first commercial sale. As amended, Pfizer has the right to terminate the Pfizer Agreement if the first commercial sale has not occurred by April 2024. The royalty period in countries in which gemcabene becomes approved for commercial sale, if any, has been extended, and the royalty rates that are payable upon achieving certain aggregate sales levels of gemcabene have increased slightly, ranging from the high single digits to the midteens depending on the level of net sales, in consideration for such extension. The terms of the Pfizer Agreement, as so amended, are summarized in Note 6 – *License Agreement*.

# 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 condensed financial statements and related 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 notes for the fiscal year ended December 31, 2017 included in our Annual Report on Form 10-K filed on March 20, 2018.

#### **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 (the "Exchange Act"). Forward-looking statements give current expectations or forecasts of future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "target," "contemplate," "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 known and unknown 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 I, Item 1A "Risk Factors" in our Annual Report on Form 10-K filed on March 20, 2018, under Part II "Other Information," Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q and in 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, changed circumstances 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 nonalcoholic fatty liver disease (NAFLD/NASH). Dyslipidemia is generally characterized by an elevation of LDL-C, or bad cholesterol, triglycerides, or fat in the blood, as well as inflammation, especially in diabesity patients. We are developing our product candidate gemcabene, a novel, once-daily, oral therapy, for high risk cardiovascular patients who are unable to achieve normal levels of LDL-C or triglycerides with currently approved therapies, primarily statin therapy, and for those patients who present with NASH. 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. In addition, gemcabene has been shown to markedly lower C-reactive protein and improve insulin sensitization. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in nearly 1,200 subjects, which we define as healthy volunteers and patients, across 25 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

We are pursuing gemcabene in the following 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, SHTG and NASH. We believe we can design an efficient development plan to provide a new treatment alternative for HoFH patients while demonstrating gemcabene's potential ability to treat patients in the most severe segment of the dyslipidemia market, which can further enhance brand awareness among key thought leaders and physicians. We are developing in parallel gemcabene for HeFH, ASCVD, SHTG and NASH given gemcabene's: (1) promising clinical data and mechanism in these indications; (2) cost-effective manufacturing process; (3) convenient oral dosing; (4) viability as adjunct combination therapy; and (5) large commercial potential. During 2016, we initiated three Phase 2b clinical trials for gemcabene in HoFH, hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins, and SHTG. We reported top line data from our 8 patient trial for HoFH (COBALT-1) in the second quarter of 2017, top line data from our 105 patient trial for hypercholesterolemia on high-intensity statin therapy including HeFH and ASCVD patients (ROYAL-1) in the third quarter of 2017, and top line data from our 91 patient trial in SHTG patients (INDIGO-1) in the second quarter of 2018. We initiated a proof-of-concept clinical trial in the first quarter of 2018. We initiated a proof-of-concept clinical trial in the first quarter of 2018 to study gemcabene in pediatric NAFLD, however, that trial was subsequently halted by the Data Safety Monitoring Board of the principal investigator in August 2018 as a result of unanticipated problems. Following the completion of our two year carcinogenicity studies conducted in connection with the partial clinical hold on gemcabene with respect to clinical trials of longer than six months in duration, the FDA requested that we provide additional data, including from a subchronic (13 we

To date, our primary activities have been conducting research and development activities, planning and conducting 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. Our net losses were \$6.7 million and \$10.5 million during the three months ended June 30, 2018 and 2017, respectively, and \$13.9 million and \$18.0 million during the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we had an accumulated deficit of \$74.4 million. 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.

Our Company was co-founded in November 2008 as a limited liability company under the name Michigan Life Therapeutics, LLC (MLT) by former Pfizer Inc. employees, including Dr. Charles Bisgaier, 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 August 2016, we consummated the initial public offering (our IPO) of our common stock pursuant to a registration statement on Form S-1. We sold an aggregate of 3,027,755 shares of our common stock, including 27,755 shares of our common stock purchased by the underwriters upon the partial exercise of their overallotment option, at a public offering price of \$10.00 per share. We received net proceeds of approximately \$26.1 million after deducting underwriting discounts and commissions and offering expenses.

On March 15, 2017, we closed a private placement of 1,324,256 units at a price of \$9.47 per unit for net proceeds of approximately \$11.3 million after deducting offering expenses. Each unit consisted of one share of our common stock and a warrant to purchase 0.75 shares of common stock. The warrants have an exercise price of \$10.40 per share and are exercisable for a period of five years from the date of issuance.

In the first quarter of 2018, we closed an underwritten public offering of 3,592,858 shares of our common stock, including 450,000 shares of our common stock purchased by the underwriters upon the partial exercise of their overallotment option, at the public offering price of \$7.00 per share. We received net proceeds of approximately \$23.1 million after deducting underwriting discounts and commissions and offering expenses.

We have funded our operations to date primarily through the issuance and sale of common stock and warrants in public offerings and a private placement, the proceeds of our term loan facility with Silicon Valley Bank and, prior to our IPO, the issuance of preferred stock and convertible notes. As of June 30, 2018, we had cash and cash equivalents of \$28.0 million.

#### **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 two categories: general and administrative and 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 on-going general and administrative expenses will fluctuate with clinical trial activity and generally trend near or above comparable prior period levels in the future to support our research and development activities, potential commercialization of gemcabene, if approved, and any future product candidates we may develop, as well as the costs of operating as a public company, including costs related to personnel and fees for legal and professional services.

# Research and Development

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

We expect that gemcabene will have higher development costs during its later stages of clinical development, as compared to costs incurred during its earlier stages of development, primarily due to the increased size and duration of the later-stage clinical trials, so we expect our research and development expenses to fluctuate relative to the number and size of ongoing clinical trials in any given period. We expect our research and development expense to generally trend below comparable prior period levels in the near term, until we initiate our Phase 3 program and then trend above comparable prior period levels 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 for the indication;
- · arrangements with contract research organizations and other service providers; and
- the efficacy and safety profile of the product candidate for the indication.

# Interest (Expense) Income

Interest (expense) income consists of cash and non-cash interest expense attributed to our Term Loan issued in 2017 based on the prime rate in effect, as well as cash interest income from short term, highly liquid money market accounts from proceeds received from the equity offerings and debt as applicable during the periods presented.

We expect to continue to incur cash and non-cash interest expense related on our Term Loan and to earn interest income from the investment of the net proceeds from our financing activities in future periods.

# Other Expense

Other expense relates to foreign currency exchange net losses over gains. 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 June 30, 2018 and December 31, 2017.

# **Results of Operations**

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

	For the Three Months Ended June 30,			For the Six Months Ended June 30,		
	2018 2017 Change			2018	2017	Change
	(in the			ousands)		
Operating expenses:						
General and administrative	\$ 2,574	\$ 4,678	\$(2,104)	\$ 4,661	\$ 6,901	\$(2,240)
Research and development	3,960	5,837	(1,877)	8,937	11,117	(2,180)
Total operating expenses	6,534	10,515	(3,981)	13,598	18,018	(4,420)
Loss from operations	(6,534)	(10,515)	3,981	(13,598)	(18,018)	4,420
Interest (expense) income	(144)	13	(157)	(304)	25	(329)
Other expense					(5)	5
Loss before income taxes	(6,678)	(10,502)	3,824	(13,902)	(17,998)	4,096
Provision (benefit) for income taxes						
Net loss	\$(6,678)	\$(10,502)	\$ 3,824	\$(13,902)	\$(17,998)	\$ 4,096

# Comparison of Three Months Ended June 30, 2018 and 2017

# General and Administrative

General and administrative expenses for the three months ended June 30, 2018 decreased to \$2.6 million compared to \$4.7 million for the three months ended June 30, 2017. The decrease in expenses from the comparable period in 2017 was primarily attributed to separation costs in the second quarter of 2017 for our former chief executive officer totaling \$0.5 million of cash compensation and \$2.1 million of non-cash share-based compensation expense resulting from the acceleration of stock option vesting. Timing of costs related to infrastructure supporting our ongoing clinical trials and public company requirements, focused primarily on personnel costs and professional services, were the other primary drivers of the activity during both quarterly periods in 2018 and 2017.

# Research and Development

Research and development expenses for the three months ended June 30, 2018 were \$4.0 million compared to \$5.8 million for the three months ended June 30, 2017. The \$1.8 million decrease was primarily attributable to reduced clinical trial activities in the second quarter of 2018 versus the comparable period in 2017.

# Interest (Expense) Income

Interest expense for the three months ended June 30, 2018 was \$0.1 million compared to interest income of \$13,000 for the three months ended June 30, 2017. Interest (expense) income for the three months ended June 30, 2018 included interest expense in connection with our Term Loan offset in part by interest income of \$55,000. Interest (expense) income for the three months ended June 30, 2017 represented only interest income as there was no outstanding debt.

#### Comparison of Six Months Ended June 30, 2018 and 2017

#### General and Administrative

General and administrative expenses for the six months ended June 30, 2018 decreased to \$4.7 million compared to \$6.9 million for the six months ended June 30, 2017. The decrease in expenses from the comparable perioded in 2017 was largely the result of separation costs in 2017 for our former chief executive officer totaling \$0.5 million of cash compensation and \$2.1 million of non-cash share-based compensation expense resulting from the acceleration of stock option vesting. Timing of costs related to infrastructure supporting our ongoing clinical trials and public company requirements, focused primarily on personnel costs and professional services, were the other primary drivers of the activity during both six month periods in 2018 and 2017.

# Research and Development

Research and development expenses for the six months ended June 30, 2018 were \$8.9 million compared to \$11.1 million for the six months ended June 30, 2017. The \$2.2 million decrease was primarily attributable to reduced clinical trial activities through the second quarter in 2018 versus the comparable period in 2017.

# Interest (Expense) Income

Interest expense for the six months ended June 30, 2018 was \$0.3 million, compared to interest income of \$25,000 for the comparable period in 2017. Interest (expense) income for the six months ended June 30, 2018 included interest expense in connection with our Term Loan offset in part by interest income of \$85,000. Interest (expense) income for the six months ended June 30, 2017 represented only interest income as there was no outstanding debt.

# **Liquidity and Capital Resources**

# **Capital Resources**

As of June 30, 2018, our principal sources of liquidity consisted of cash and cash equivalents of approximately \$28.0 million. Our cash and cash equivalents are invested in cash deposits and money market accounts.

We have not generated any revenue, and we anticipate that we will continue to incur losses for the foreseeable future. We have funded our operations to date primarily through the issuance and sale of common stock and warrants in public offerings and a private placement, proceeds from our term loan facility with Silicon Valley Bank and, prior to our IPO, the issuance of preferred stock and convertible notes in private placements. See Note 4 — Debt, included in "Item 8 — Financial Statements and Supplementary Data" included in our Annual Report on Form 10-K filed on March 20, 2018 for a description of the convertible notes we issued prior to our IPO.

· In the first quarter of 2018, we completed the Follow-On Offering of 3,592,858 shares of our common stock, including 450,000 shares of our common stock purchased by the underwriters upon the partial exercise of their overallotment option, at the public offering price of \$7.00 per share. We received net proceeds of approximately \$23.1 million after deducting underwriting discounts and commissions and offering expenses.

- · On July 24, 2017, we entered into a Loan and Security Agreement with Silicon Valley Bank (SVB), which was amended on July 31, 2018 (collectively, the Loan Agreement). The Loan Agreement established a term loan facility in the aggregate principal amount of up to \$15.0 million (the Term Loan) to be funded in several tranches. We drew \$10.0 million under the Loan Agreement on July 24, 2017. See "—Liquidity and Capital Resource Requirements" below for a description of the availability of Tranche C, repayment terms and certain other material terms of the Loan Agreement.
- On March 15, 2017, we completed a private placement of 1,324,256 units at a price of \$9.47 per unit for net proceeds of approximately \$11.3 million after deducting offering expenses. Each unit consisted of one share of our common stock and a warrant to purchase 0.75 shares of common stock. The warrants have an exercise price of \$10.40 per share and are exercisable for a period of five years from the date of issuance. On April 20, 2017, the registration statement on Form S-1 (File No 333-217296) for the resale of the shares of common stock issued in the private placement and the shares of common stock to be issued upon exercise of the warrants issued in the private placement was declared effective by the SEC, and on September 1, 2017, we filed a post-effective amendment to convert the registration statement into Form S-3 for the registration of any unsold Private Placement shares, which included an updated prospectus relating to such unsold shares.
- In August 2016, we closed our IPO. We sold an aggregate of 3,027,755 shares of our common stock, including 27,755 shares of our common stock purchased by the underwriters upon the partial exercise of their overallotment option, at a public offering price of \$10.00 per share. We received net proceeds of approximately \$26.1 million after deducting underwriting discounts and commissions and offering expenses. All of our outstanding preferred stock and convertible notes outstanding prior to our IPO converted into shares of our common stock immediately prior to the closing of the IPO.

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
- · continue to operate as a public company.

#### Cash Flows

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

	For the Six Months Ended June 30,	For the Six Months Ended June 30,		
	2018 2017			
	(in thousands)			
Net cash used in operating activities	\$ (13,514) \$ (12,842)			
Net cash provided by (used in) investing activities				
Net cash provided by financing activities	23,080 11,300			
Net increase (decrease) in cash	\$ 9,566 \$ (1,542)			

# **Cash Flow from Operating Activities**

For the six months ended June 30, 2018, cash used in operating activities of \$13.5 million was attributable to a net loss of \$13.9 million as adjusted by \$1.9 million in share-based compensation and non-cash interest expense of \$0.2 million offset by a net change of \$1.7 million in our operating assets and liabilities. The change in operating assets and liabilities was primarily attributable to a net decrease in our accounts payable, accrued liabilities and prepaid expenses associated with fluctuations in our operating activities.

For the six months ended June 30, 2017, cash used in operating activities of \$12.8 million was attributable to a net loss of \$18.0 million offset by \$3.8 million in share-based compensation and a net change of \$1.4 million in our net operating assets and liabilities. The change in operating assets and liabilities was primarily attributable to an increase in our accounts payable and decrease in our prepaid expenses offset in part by a decrease in accrued and other liabilities associated with fluctuations in our operating expense payments.

#### 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 six months ended June 30, 2018 of \$23.1 million related primarily to proceeds received from our Follow-On Offering, net of discounts, commissions and other costs totaling \$2.1 million paid through June 30, 2018.

Net cash provided by financing activities during the six months ended June 30, 2017 was \$11.3 million related primarily to the proceeds from our Private Placement, net of discounts, commissions and other costs totaling \$1.3 million paid through June 30, 2017.

# Liquidity and Capital Resource Requirements

Based on current operating plans, we believe the approximately \$28.0 million of cash on hand, will be sufficient to fund our operations into the fourth quarter of 2019. 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.

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 had \$10.2 million outstanding under our Term Loan with SVB on June 30, 2018. See "—Term Loan" below. Under our Loan Agreement with SVB, an additional tranche of \$5.0 million may be available to be drawn by us through November 30, 2018 conditioned on the occurrence of a positive clinical trial event and a pre-clinical event, as well as a positive Phase 2 NASH event. As discussed above, the FDA has asked that we complete additional pre-clinical studies and submit additional data in connection with the partial clinical hold on gemcabene; accordingly, we do not expect a pre-clinical event to occur prior to November 30, 2018. We do not have any other committed external source of funds.

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. 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. Similar to the restrictions under our Loan Agreement described below, additional 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.

#### Term Loan

Pursuant to our Loan Agreement described above, as amended on July 31, 2018, all amounts advanced under the Term Loan mature on February 1, 2021 and have an interest-only monthly payment period through November 1, 2018, which may be extended to February 1, 2019 upon the occurrence of both a positive clinical trial event and a pre-clinical event, as well as a positive Phase 2 NASH event, as determined by SVB. Following the interest-only payment period, we will begin making monthly payments of principal and interest until the maturity date. Interest will accrue on the unpaid principal balance at a floating per annum rate equal to the prime rate, except that, following an event of default, interest will accrue at a rate up to 5% above the rate that is otherwise applicable. Our obligations under the Loan Agreement may be accelerated by SVB upon the occurrence of an event of default. An event of default includes customary events for a financing arrangement of this type, including, without limitation, payment defaults, defaults in the performance of affirmative or negative covenants, bankruptcy or related defaults, defaults on certain other indebtedness, defaults under certain other agreements, the imposition of judgments or penalties, the material inaccuracy of representations or warranties, material adverse changes and revocations of government approvals.

The Loan Agreement requires us to pay the following fees: (i) upon the maturity, acceleration or prepayment of the Term Loan, a final payment fee of 10% of the funded principal amount of the Term Loan, (ii) a success fee of 3.5% of the funded principal amount of the Term Loan upon the occurrence of certain contingent events as defined in the Loan Agreement, and (iii) upon termination of the Loan Agreement prior to the maturity date for any reason, a prepayment fee equal to 2% (if such prepayment occurs prior to July 31, 2019) or 1% (if such prepayment occurs thereafter) of the funded principal amount of the Term Loan.

In the event a positive clinical trial event had not occurred by March 31, 2018, on such date, we would have been required to either (i) provide cash security and maintain a cash balance in a restricted account at SVB in an amount of at least 50% of the amounts we owe to SVB or (ii) prepay the Term Loan in its entirety. On November 10, 2017, we provided SVB evidence of a positive clinical trial event. In the event a pre-clinical event does not occur on or prior to September 30, 2019

or, if at any time prior to a pre-clinical event, our unrestricted cash balance at SVB is less than \$18 million, on such date, we must either (i) provide cash security and maintain a cash balance in a restricted account at SVB in an amount of at least 100% of the amounts we owe to SVB or (ii) prepay the Term Loan in its entirety. In each case, if we choose to prepay the Term Loan, in addition to the repayment of the outstanding principal and accrued and unpaid interest, we are required to pay the final payment fee and, if applicable, the success fee, but not the prepayment fee.

Subject to certain exceptions, the Loan Agreement contains covenants prohibiting us from, among other things: (a) disposing of our properties or assets; (b) liquidating or dissolving; (c) engaging in any business other than the business currently engaged in by us or reasonably related thereto; (d) engaging in business combinations or acquisitions or permitting or suffering any change in control; (e) incurring any additional indebtedness; (f) allowing any lien or encumbrance on any of our property; (g) paying any dividends or distributions; (h) entering into transactions with affiliates; and (i) making payment on subordinated debt.

In addition, we issued a warrant to purchase 36,000 shares of our common stock at an exercise price of \$7.47 per share to SVB on July 31, 2018 in connection with the first amendment under the Loan Agreement. The warrant is immediately exercisable and has a term of ten years. The exercise price and number and type of shares underlying the warrant are subject to adjustment upon specified events, including any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. The warrant contains a "cashless exercise" feature that allows SVB to exercise the warrant without a cash payment to the Company, on a net issuance basis, based upon the fair market value of the Company's common stock at the time of exercise, upon the terms set forth therein.

# **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 in Note 2 — "Summary of Significant Accounting Policies" to our condensed financial statements included in Part I "Financial Information", Item I "Financial Statements" of this Quarterly Report on Form 10-Q.

During the three and six months ended June 30, 2018, 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 Annual Report on Form 10-K filed on March 20, 2018.

# **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— "Summary of Significant Accounting Policies" to our condensed financial statements included in Part I "Financial Information", Item I "Financial Statements" of this Quarterly Report on Form 10-Q for a discussion of recently issued accounting pronouncements.

# ITEM 3. OUANTITATIVE AND OUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

# 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 Exchange Act as of June 30, 2018. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2018.

# **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 June 30, 2018, 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

In addition to the other information set forth elsewhere in this Current Report on Form 10-Q, you should carefully consider the factors set forth below and the other factors discussed in Part I, Item 1A "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2017. Those factors, if they were to occur, could cause our actual results to differ materially from those expressed in our forward-looking statements in this report, and materially adversely affect our financial condition or future results. Although we are not aware of any other factors that we currently anticipate will cause our forward-looking statements to differ materially from our future actual results, or materially affect the Company's financial condition or future results, additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results.

Gemcabene is subject to a partial clinical hold with respect to clinical trials of longer than six months in duration until the FDA determines to release such hold, 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 required us to conduct two-year rat and mouse carcinogenicity studies. The FDA has issued these notices to all sponsors of product candidates with PPAR properties based on preclinical studies. We submitted the results of our two-year rat and mouse carcinogenicity studies to the FDA, together with results from a short-term, 8 day study where, in PPAR $\alpha$  knockout mice, gemcabene did not induce known markers of peroxisome proliferation, providing evidence that gemcabene works through PPAR $\alpha$ . In response the FDA has requested that, as part of a complete response, we provide additional data including a subchronic (13 week) study in PPAR $\alpha$  knock-out mice and PPAR transactivation assays using monkey and canine PPAR isoforms, to further understand the human relevance of the preclinical findings. We have initiated plans to conduct these required studies and expect to submit the additional results to the FDA in the second quarter of 2019.

The future clinical development of gemcabene may be delayed due to these clinical restrictions and additional oversight by the FDA, as occurred when the FDA requested the additional data beyond the results of our two-year rat and mouse carcinogenicity studies. If the results of the subchronic (13 week) study in PPARα knock-out mice and PPAR transactivation assays using monkey and canine PPAR isoforms that we plan to conduct 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 further delayed. Also, the findings in our preclinical studies could impact the NDA review, and, if approved, labeling and use of gemcabene.

Finally, if the FDA has not lifted the partial clinical hold with respect to clinical trials of longer than six months in duration for gemcabene by September 30, 2019, under our Loan Agreement, we must either (i) provide cash security and maintain a cash balance in a restricted account at SVB in an amount of at least 100% of the amounts we owe to SVB or (ii) prepay the Term Loan in its entirety.

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 previously completed clinical trials, such as the unanticipated problems that occurred in connection with the pediatric NAFLD study), 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. See "—Gemphire's Phase 2a clinical trial of gemcabene in Pediatric NAFLD was terminated by the Data and Safety Monitoring Board (DSMB) of the principal investigator following the occurrence of unanticipated problems. This trial termination and the unexpected problems could have negative impacts on the clinical development of gemcabene" below. Prior to the pediatric NAFLD trial, 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 delay or prevent regulatory approval and 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.

Gemphire's Phase 2a clinical trial of gemcabene in Pediatric NAFLD was terminated by the Data and Safety Monitoring Board (DSMB) of the principal investigator following the occurrence of unanticipated problems. This trial termination and the unexpected problems could have negative impacts on the clinical development of gemcabene.

We announced on August 10, 2018 that the DSMB at Emory University School of Medicine overseeing the investigator-led open label Phase 2a proof-of-concept trial evaluating gemcabene in pediatric patients with non-alcoholic fatty liver disease (NAFLD) recommended that the trial be terminated due to unanticipated problems. Data on the first three patients who underwent 12 weeks of treatment showed that all three experienced an increase in liver fat content, as measured by MRI-PDFF, and demonstrated increases in ALT. The increase in liver fat was deemed an unexpected problem by the trial investigator because it was an unexpected consistent pattern of worsening of the disease, rather than improvement, creating risk to the patients, which the investigator believed was likely due to the drug. Other patients currently enrolled in the trial have now been taken off gemcabene and early termination visits are being scheduled. The DSMB has recommended additional follow-up of the study subjects to gather additional safety data. The DSMB will provide us with a written report of their findings in the future once all the patient results have been collated and analyzed.

Gemphire intends to work closely with the physicians at the clinical trial site, and other KOLs to analyze all of the results and identify potential reasons for these unexpected problems in the pediatric NAFLD study but cannot assure you that it will be able to determine the reasons for the unexpected problems

Following the termination of the pediatric NAFLD trial, the investigator of the ongoing Phase 2a FPL study is closely monitoring the patients in the study while waiting for MRI-PDFF scans to be reviewed before dosing additional patients. MRI-PDFF scans or other follow-up tests of patients in the pediatric NAFLD, FPL or other trials may show similar increases in liver fat content or ALT or other undesirable side effects.

Gemphire cannot determine the impact that termination of, or the occurrence of the unexpected problems in, the pediatric NAFLD study will have on the FPL study and the investigator in the FPL study may determine to discontinue the study whether or not MRI-PDFF scans of the patients show increases in liver fat, ALT or other undesirable side effects. The unanticipated problems in the pediatric NAFLD patients may also impact the enrollment of pediatric and/or adult patients in future studies. We cannot assure you that the unexpected problems observed in the pediatric NAFLD trial will not be seen in the FPL or future trials or that serious adverse events (SAEs) will not occur in future trials. We also cannot assure you that the unexpected problems observed in the pediatric NAFLD trial will not result in the FDA requesting additional analyses of our previously completed clinical trials, including the three Phase 2b trials in dyslipidemia completed in 2017 and 2018.

If gemcabene is associated with adverse effects or undesirable side effects in preclinical testing or clinical trials or has characteristics that are unexpected in preclinical testing or clinical trials, we may need to consider protocol amendments, petition the FDA for Special Protocol Assessment (SPA), modify the scope of our Phase 3 programs to pursue more focused indications in which the undesirable side effects or other characteristics may be less prevalent, less severe or provide a better understanding from a risk benefit perspective, or abandon the development of the compound. In pharmaceutical development, many compounds that initially show promise in early-stage testing are later found to cause adverse effects that prevent further development of the compound.

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 certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Under the license agreement, as amended in August 2018, either party may terminate the license agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the license agreement in the event that (i) the Company or any of its affiliates or sublicensees contests or challenges, or supports or assists 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 the license agreement or (ii) the Company or any of its affiliates or sublicensees fails to achieve the first commercial sale in at least one country by April 16, 2024. Furthermore, upon termination of the license agreement by Pfizer for any of the foregoing reasons, we grant Pfizer, pursuant to the license agreement, a non-exclusive, fully paid-up, royalty free, worldwide, transferrable, perpetual and irrevocable license to use any intellectual property rights arising from the development or commercialization of gemcabene by the Company and any trademarks identifying gemcabene and agree to transfer regulatory filings and approvals to Pfizer or permit Pfizer to cross-reference and rely on such regulatory filings and approvals for gemcabene.

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 and the historical preclinical and clinical data package 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 retains the right to make, use and import gemcabene solely for internal research purposes.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our Loan Agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

We entered into a Loan and Security Agreement with SVB on July 24, 2017 and amended the Loan and Security Agreement on July 31, 2018 (as so amended, the Loan Agreement). The Loan Agreement established a term loan facility in the aggregate principal amount of up to \$15.0 million (the Term Loan) to be funded in several tranches. We drew \$10.0 million under the Loan Agreement on July 24, 2017. Conditioned on the occurrence of both a positive clinical trial event, a pre-clinical event and a positive Phase 2 NASH event, an additional tranche of \$5.0 million may be available to be drawn by us through November 30, 2018, unless a default occurs before such date. "Positive clinical trial event" means the receipt by SVB of a written electronic communication from a member of our board of directors (i) stating that the board of directors has determined that the results from either (a) our ROYAL-1 clinical trial or (b) our INDIGO-1 clinical trial are sufficient to support the development plan for submission of a new drug application with FDA and continued development of gemcabene and (ii) attaching a copy of the press release announcing the foregoing. On November 10, 2017, we provided SVB evidence of a positive clinical trial event. "Pre-clinical event" means the receipt by SVB of a written electronic communication from our chief executive officer or chief financial officer, together with supporting documentation from the FDA, that the FDA has lifted the partial clinical hold with respect to clinical trials of longer than six months in duration for gemcabene. "Positive Phase 2 NASH event" means public disclosure by the Company of evidence satisfactory to SVB, in its sole but reasonable discretion, that the Company has received positive Phase 2 interim data on either its adult familial partial lipodystrophy proof-of-concept clinical trial or its pediatric NAFLD proof-of-concept clinical trial. As discussed above, the FDA has asked that we complete additional pre-clinical studies and submit additional data in connection with

All amounts advanced under the Term Loan mature on February 1, 2021 and have an interest-only monthly payment period through November 1, 2018, which may be extended to February 1, 2019 upon the occurrence of both a positive clinical trial event and a pre-clinical event. Following the interest-only payment period, we will begin making monthly payments of principal and interest until the maturity date. Interest will accrue on the unpaid principal balance at a floating per annum rate equal to the prime rate, except that, following an event of default, interest will accrue at a rate up to 5% above the rate that is otherwise applicable.

Subject to certain exceptions, the Loan Agreement contains covenants prohibiting us from, among other things: (a) disposing of our properties or assets; (b) liquidating or dissolving; (c) engaging in any business other than the business currently engaged in by us or reasonably related thereto; (d) engaging in business combinations or acquisitions or permitting or suffering any change in control; (e) incurring any additional indebtedness; (f) allowing any lien or encumbrance on any of our property; (g) paying any dividends or distributions; (h) entering into transactions with affiliates; and (i) making payment on subordinated debt. Our business may be adversely affected by these restrictions on our ability to operate our business.

In the event a pre-clinical event does not occur on or prior to September 30, 2019 or, if at any time prior to a pre-clinical event, our unrestricted cash balance at SVB is less than \$18,000,000, we must either (i) provide cash security and maintain a cash balance in a restricted account at SVB in an amount of at least 100% of the amounts we owe to SVB or (ii) prepay the Term Loan in its entirety.

Our obligations under the Loan Agreement may be accelerated by SVB upon the occurrence of an event of default. An event of default includes customary events for a financing arrangement of this type, including, without limitation, payment defaults, defaults in the performance of affirmative or negative covenants, bankruptcy or related defaults, defaults on certain other indebtedness, defaults under certain other agreements, the imposition of judgments or penalties, the material inaccuracy of representations or warranties, material adverse changes and revocations of government approvals. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time such event of default were to occur, if ever. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. SVB could also exercise its security interest, which collateral includes substantially all of our assets whether currently owned or hereafter acquired, excluding our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

The restrictive covenants under our Loan Agreement, including the cash balance covenant described above, could limit our ability to obtain future financing, withstand a future downturn in our business or the economy in general or otherwise conduct necessary corporate activities. The financial and restrictive covenants contained in our Loan Agreement could also adversely affect our ability to respond to changing economic and business conditions and place us at a competitive disadvantage relative to other companies that may be subject to fewer restrictions. Transactions that we may view as important opportunities, such as acquisitions, may be subject to the consent of SVB, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

Our common stock may be delisted from the Nasdaq Global Market if we are unable to maintain compliance with Nasdaq's continued listing standards.

Nasdaq imposes, among other requirements, continued listing standards including minimum bid and public float requirements. The price of our common stock must trade at or above \$1.00 to comply with the minimum bid requirement for continued listing on the Nasdaq Global Market. If our stock trades at closing bid prices of less than \$1.00 for a period in excess of 30 consecutive business days, Nasdaq could send a deficiency notice to us for not remaining in compliance with the minimum bid listing standard. On August 10, 2018, the closing price of our common stock was \$1.80. If the closing bid price of our common stock fails to meet Nasdaq's minimum closing bid price requirement, or if we otherwise fail to meet any other applicable requirements of the Nasdaq Global Market and we are unable to regain compliance, Nasdaq may make a determination to delist our common stock. Any delisting of our common stock could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Furthermore, if our common stock were delisted it could adversely affect our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by investors.

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

(a) Sales of Unregistered Securities None.

# (b) Use of Proceeds

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 \$2.1 million which, when added to the underwriting discounts and commissions, amounted to total expenses of approximately \$4.2 million. Thus, the net offering proceeds, after deducting underwriting discounts and commissions and offering expenses, were approximately \$26.1 million.

We estimate that we have used all of the net proceeds from the IPO, primarily to fund the Phase 2b clinical program of gemcabene in HoFH, hypercholesterolemia, including HeFH and ASCVD patients on maximally tolerated statins, and SHTG, manufacturing-related activities for gemcabene and pre-clinical studies and related activities.

(c) Stock Repurchases

None.

# ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

# ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

# ITEM 5. OTHER INFORMATION

Not Applicable.

# ITEM 6. EXHIBITS

EXHIBIT	
NUMBER	DESCRIPTION OF DOCUMENT
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
	<u>August 10, 2016).</u>
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).
4.1	Warrant to Purchase Stock, dated July 31, 2018, by and between Gemphire Therapeutics Inc. and Silicon
	Valley Bank (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8- K,
	<u>File No. 001-37809, filed on August 6, 2018).</u>
10.1*	Amendment No. 1 to the Gemphire Therapeutics Inc. Inducement Plan (incorporated by reference to
	Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on April 12,
	<u>2018).</u>
10.2*	Employment Agreement between Gemphire Therapeutics Inc. and Dr. Steven Gullans dated May 1, 2018
	(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-
	37809, filed on May 3, 2018).
10.3*	Amendment to the Gemphire Therapeutics Inc. Amended and Restated 2015 Equity Incentive Plan
	(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, File No. 001-
	37809, filed on May 24, 2018).
10.4+	Amended and Restated License Agreement, dated August 2, 2018, by and between Gemphire
	Therapeutics Inc. and Pfizer Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current
10.5	Report on Form 8-K, File No. 001-37809, filed on August 6, 2018).
10.5	First Amendment to Loan and Security Agreement dated July 31, 2018 by and between Gemphire
	Therapeutics Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Registrant's
24.4	Current Report on Form 8- K, File No. 001-37809, filed on August 6, 2018).
31.1	Certification of Principal Executive Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as
21.2	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
22.1	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
101.INS	1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. XBRL Instance Document
101.INS 101.SCH	XBRL Taxonomy Extension Schema Document
101.SCH 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.CAL 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.DEF 101.LAB	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.PKE *	
+	Indicates management contract or compensatory plan  Portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been
'	separately filed with the Securities and Exchange Commission
	separatery rifeti with the securities and exchange Commission

# **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.

SIGNATURE	TITLE	DATE
/s/ STEVEN GULLANS Steven Gullans	President and Chief Executive Officer (Principal Executive Officer)	August 14, 2018
/s/ JEFFREY S. MATHIESEN Jeffrey S. Mathiesen	Chief Financial Officer (Principal Financial and Accounting Officer)	August 14, 2018
	40	

# 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, Steven Gullans, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Gemphire Therapeutics Inc. for the quarterly period ended June 30, 2018;
- 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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: August 14, 2018 /s/ STEVEN GULLANS

Name: Steven Gullans

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

# 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 June 30, 2018;
- 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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: August 14, 2018 /s/ JEFFREY S. MATHIESEN

Name: Jeffrey S. Mathiesen Title: Chief Financial Officer (Principal Financial Officer)

# 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, Steven Gullans, 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 June 30, 2018, 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/ STEVEN GULLANS	/s/ JEFFREY S. MATHIESEN		
President and Chief Executive Officer	Chief Financial Officer		
Dated: August 14, 2018	Dated: August 14, 2018		
Commission and is not to be incorporated by reference	relates, is not deemed filed with the Securities and Exchange ce into any filing of Gemphire Therapeutics Inc. under the made before or after the date of the report, irrespective of any		