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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 10-Q**

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**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2017

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
COMMISSION FILE NUMBER 001-36576



**MARINUS PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

20-0198082  
(I.R.S. Employer  
Identification No.)

170 N. Radnor Chester Rd, Suite 250  
Radnor, PA 19087  
(Address of registrant's principal executive offices)

Registrant's telephone number, including area code: (484) 801-4670

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company)

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of October 30, 2017 was: 40,430,196.

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**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY  
INDEX TO FORM 10-Q  
FOR THE QUARTER ENDED SEPTEMBER 30, 2017**

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**PART I**  
**FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY**

**CONSOLIDATED BALANCE SHEETS**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	<u>September 30,</u> <u>2017</u>	<u>December 31, 2016</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 37,530	\$ 26,178
Short-term investments	5,435	3,922
Prepaid expenses and other current assets	582	199
Total current assets	43,547	30,299
Property and equipment, net	1,172	1,148
Investments	19,938	—
Total assets	<u>\$ 64,657</u>	<u>\$ 31,447</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 634	\$ 2,809
Accrued expenses	1,796	1,775
Current portion of notes payable	—	3,500
Total current liabilities	2,430	8,084
Notes payable	—	1,743
Other long-term liabilities	127	141
Total liabilities	2,557	9,968
Stockholders' equity:		
Preferred stock, \$0.001 par value; 25,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized, 40,459,427 issued and 40,430,196 outstanding at September 30, 2017 and 19,734,351 issued and 19,705,120 outstanding at December 31, 2016	40	20
Additional paid-in capital	202,067	147,288
Treasury stock at cost, 29,231 shares at September 30, 2017 and December 31, 2016	—	—
Accumulated other comprehensive loss	(18)	—
Accumulated deficit	(139,989)	(125,829)
Total stockholders' equity	62,100	21,479
Total liabilities and stockholders' equity	<u>\$ 64,657</u>	<u>\$ 31,447</u>

See accompanying notes to consolidated financial statements.

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
<b>Expenses:</b>				
Research and development	\$ 2,642	\$ 4,840	\$ 9,032	\$ 17,593
General and administrative	<u>1,571</u>	<u>1,529</u>	<u>5,074</u>	<u>4,719</u>
Loss from operations	(4,213)	(6,369)	(14,106)	(22,312)
Interest income	45	36	116	93
Interest expense	(3)	(118)	(159)	(365)
Other income (expense)	<u>1</u>	<u>(13)</u>	<u>(11)</u>	<u>(44)</u>
Net loss	<u>\$ (4,170)</u>	<u>\$ (6,464)</u>	<u>\$ (14,160)</u>	<u>\$ (22,628)</u>
<b>Per share information:</b>				
Net loss per share of common stock—basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.33)</u>	<u>\$ (0.60)</u>	<u>\$ (1.16)</u>
Basic and diluted weighted average shares outstanding	<u>28,666,656</u>	<u>19,509,220</u>	<u>23,531,745</u>	<u>19,494,424</u>
Net loss	\$ (4,170)	\$ (6,464)	\$ (14,160)	\$ (22,628)
<b>Other comprehensive loss:</b>				
Unrealized loss on available-for-sale securities	<u>(18)</u>	<u>—</u>	<u>(18)</u>	<u>—</u>
Total comprehensive loss	<u>\$ (4,188)</u>	<u>\$ (6,464)</u>	<u>\$ (14,178)</u>	<u>\$ (22,628)</u>

See accompanying notes to consolidated financial statements.

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (14,160)	\$ (22,628)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	35	16
Stock-based compensation expense	2,251	2,276
Amortization of debt issuance costs	4	5
Amortization of discount on investments	(3)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(383)	1,054
Accounts payable and accrued expenses	(2,080)	556
Net cash used in operating activities	<u>(14,336)</u>	<u>(18,721)</u>
<b>Cash flows from investing activities</b>		
Purchases of investments	(24,892)	(2,434)
Maturities of short-term investments	3,426	4,225
Purchases of property and equipment	(192)	(643)
Net cash (used in) provided by investing activities	<u>(21,658)</u>	<u>1,148</u>
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options	—	123
Principal payments of notes payable	(5,247)	(1,210)
Proceeds from equity offerings, net of offering costs	52,593	(167)
Net cash provided by (used in) financing activities	<u>47,346</u>	<u>(1,254)</u>
Net increase (decrease) in cash and cash equivalents	11,352	(18,827)
Cash and cash equivalents—beginning of period	26,178	51,722
Cash and cash equivalents—end of period	<u>\$ 37,530</u>	<u>\$ 32,895</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 184	\$ 360
Payment on notes payable in accounts payable	\$ —	\$ 43
Property and equipment in accounts payable	\$ —	\$ 6
Accrued equity offering costs	\$ 45	\$ —

See accompanying notes to consolidated financial statements.

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

**1. Description of the Business and Liquidity**

We are a clinical stage biopharmaceutical company focused on developing and commercializing innovative therapeutics to treat epilepsy and neuropsychiatric disorders. Our clinical stage product candidate, ganaxolone, is a positive allosteric modulator of the GABA<sub>A</sub> receptor being developed in three different dose forms (intravenous, oral capsule and oral liquid) intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings and in both in-patient and self-administered settings. The GABA<sub>A</sub> receptor is a well-characterized target in the brain known for both anti-seizure, anti-depression and anti-anxiety effects. Our primary focus to date has been directed towards developing business strategies, conducting research and development activities, and conducting preclinical testing and human clinical trials for our product candidate.

**Liquidity**

We have not generated any product revenues and have incurred operating losses since inception. There is no assurance that profitable operations will ever be achieved, and if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of our product candidates will require significant additional financing. Our accumulated deficit as of September 30, 2017 was \$140.0 million and we expect to incur substantial losses in future periods. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. We have not generated positive cash flows from operations, and there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our planned product candidates.

In connection with the closing of a secondary public offering during the third quarter of 2017, we issued a total of 10,733,334 shares of common stock resulting in aggregate net proceeds, after underwriting discounts and commissions and other estimated offering expenses, of \$37.7 million. We believe that our cash, cash equivalents and investment balance as of September 30, 2017 is adequate to fund our operations for at least the next 12 months.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The unaudited interim consolidated financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all information and disclosures necessary for a presentation of our financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States of America (GAAP) for annual financial statements. In the opinion of management, these unaudited interim consolidated financial statements reflect the elimination of all intercompany accounts and transactions and all adjustments, consisting primarily of normal recurring accruals, necessary for a fair presentation of our financial position and results of operations and cash flows for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. These unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2016 and accompanying notes thereto included in our annual report on Form 10-K filed with the SEC on March 13, 2017.

**Use of Estimates**

The preparation of financial statements in conformity with GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from such estimates.

**Research and development costs**

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, monitoring visits, clinical site activations, or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be. Research and development costs are net of state research and development tax credits which were sold to a third party for cash in the amount of \$0.4 million for the three and nine months ended September 30, 2017.

**Recent Accounting Pronouncements**

In February 2016, the Financial Accounting Standard Board (FASB) issued Accounting Standards Update (ASU) 2016-02, *Leases*, which requires that lease arrangements longer than 12 months result in an entity recognizing an asset and liability. The updated guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. We have not evaluated the impact of the updated guidance on our interim or annual consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows*, which amends the guidance in Accounting Standards Codification (ASC) 230 on the classification of certain cash receipts and payments in the statement of cash flows. The primary purpose of the ASU is to reduce the diversity in practice that has resulted from the lack of consistent principles on this topic. The guidance in the ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We do not expect the adoption of this ASU to have a material effect on our interim or annual consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Scope of Modification Accounting*, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. For all entities, the ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017, with early adoption permitted. We do not expect the adoption of this ASU to have a material effect on our interim or annual consolidated financial statements.

**3. Fair Value Measurements**

FASB accounting guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The accounting guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, we use quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources.

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 — Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

*Valuation Techniques - Level 2 Inputs*

The Company estimates the fair values of its financial instruments categorized as level 2 in the fair value hierarchy, including U.S. Treasury securities, by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, benchmark yields, issuer credit spreads, benchmark securities, and other observable inputs. The Company obtains a single price for each financial instrument and does not adjust the prices obtained from the pricing service. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods, obtaining market values from other pricing sources and comparing them to the share prices presented by the third-party pricing services. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its third-party pricing services as of September 30, 2017.

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
<b>September 30, 2017</b>				
<b>Assets</b>				
Money market funds (cash equivalents)	\$ 37,171	\$ —	\$ —	\$ 37,171
Certificates of deposit	496	—	—	496
U.S. Treasury securities	—	24,877	—	24,877
Total assets	<u>\$ 37,667</u>	<u>\$ 24,877</u>	<u>\$ —</u>	<u>\$ 62,544</u>
<b>December 31, 2016</b>				
<b>Assets</b>				
Money market funds (cash equivalents)	\$ 25,629	\$ —	\$ —	\$ 25,629
Certificates of deposit	3,922	—	—	3,922
Total assets	<u>\$ 29,551</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 29,551</u>



**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)****4. Accrued Expenses**

At September 30, 2017 and December 31, 2016 accrued expenses consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Payroll and related costs	\$ 984	\$ 880
Clinical trials and drug development	536	681
Professional fees	248	101
Other	28	113
Total accrued expenses	\$ 1,796	\$ 1,775

**5. Notes Payable**

In 2014, we borrowed an aggregate of \$7.0 million in connection with a Loan and Security Agreement, as amended (LSA). In July 2017, we paid in full the entire outstanding term loans balance of \$3.5 million and accrued interest, with no penalty for prepayment. Through July 2017 and pursuant to the terms of the LSA, we were required to make monthly interest payments for all outstanding borrowings at an interest rate equal to the greater of (a) prime rate plus 3.25% or (b) 6.5% and monthly principal payments of 1/24th of our principal borrowings plus interest.

Interest expense related to the term loans was \$3 thousand and \$159 thousand for the three and nine months ended September 30, 2017. As of September 30, 2017, we had no accrued interest.

**6. Loss Per Share of Common Stock**

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, convertible notes payable, warrants, stock options, and unvested restricted stock, which would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation. These potentially dilutive securities are more fully described in Note 8, and summarized in the table below:

	September 30,	
	2017	2016
Restricted stock	239,800	196,275
Stock options	2,910,761	2,238,197
	3,150,561	2,434,472

**7. Investments**

As of September 30, 2017, our investments consisted of U.S. Treasury securities, maturing at various dates through January 2019, and certificates of deposit with various financial institutions maturing in November 2017. U.S. Treasury securities are classified as short- or long-term investments on our consolidated balance sheets based on maturity and certificates of deposit are classified as short-term investments on our consolidated balance sheets. U.S. Treasury securities are classified as available-for-sale and are recorded at fair value. Certificates of deposits are classified as held-to-maturity and are recorded at amortized cost, which approximates fair value.

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

As of September 30, 2017, all five of our U.S. Treasury securities were in an unrealized loss position, none of which had been in an unrealized loss position for 12 months or greater. Total amortized cost and fair value were each \$24.9 million as of September 30, 2017. Based on review of these securities, we believe that the cost basis of these available-for-sale securities is recoverable and that there were no other-than-temporary impairments on these securities as of September 30, 2017.

**8. Stockholders' Equity**

In 2005, we adopted the 2005 Stock Option and Incentive Plan (2005 Plan) that authorizes us to grant options, restricted stock and other equity-based awards. As of September 30, 2017, 430,922 options to purchase shares of common stock were outstanding pursuant to grants in connection with the 2005 Plan. No additional shares are available for issuance under the 2005 Plan.

Effective August 2014, we adopted our 2014 Equity Incentive Plan, amended in May 2017 (2014 Plan), that authorizes us to grant options, restricted stock, and other equity-based awards, subject to adjustment in accordance with the 2014 Plan. The amount, terms of grants, and exercisability provisions are determined and set by our board of directors. As of September 30, 2017, 2,479,839 options to purchase shares of common stock and 239,800 shares of restricted stock were outstanding pursuant to grants in connection with the 2014 Plan, and 1,258,825 shares of common stock were available for future issuance. The amount, terms of grants, and exercisability provisions are determined and set by our board of directors.

**Stock Options**

There were 2,910,761 stock options outstanding as of September 30, 2017 at a weighted-average exercise price of \$4.99 per share. During the nine months ended September 30, 2017, 829,800 options were granted to employees, directors and consultants at a weighted-average exercise price of \$1.27 per share, and 158,083 options were forfeited at a weighted-average exercise price of \$7.85 per share.

Total compensation cost recognized for all stock option awards in the statements of operations is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 172	\$ 265	\$ 542	\$ 710
General and administrative	381	487	1,336	1,518
Total	\$ 553	\$ 752	\$ 1,878	\$ 2,228

**Restricted Stock**

All issued and outstanding restricted shares of common stock are time-based, and become vested between one and three years after the grant date. Compensation expense is recorded ratably over the requisite service period. Compensation expense related to restricted stock is measured based on the fair value using the closing market price of our common stock on the date of the grant.

During the nine months ended September 30, 2017, we issued 245,200 restricted shares of common stock to employees, directors and consultants. As of September 30, 2017, there were 239,800 restricted shares of common stock outstanding, and 179,700 shares vested during the nine months ended September 30, 2017.

**MARINUS PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

Total compensation cost recognized for all restricted stock awards in the statements of operations is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 51	\$ 19	\$ 100	\$ 19
General and administrative	128	29	273	29
Total	<u>\$ 179</u>	<u>\$ 48</u>	<u>\$ 373</u>	<u>\$ 48</u>

***Equity Distribution Agreement***

In August 2015, we entered into an Equity Distribution Agreement (EDA) with JMP Securities LLC (JMP), under which JMP, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell over a three-year period from the execution of the agreement up to a maximum of \$35 million of shares of our common stock. We are not required to sell any shares at any time during the term of the EDA.

The EDA will terminate upon the earliest of: (1) the sale of all shares subject to the EDA, (2) August 15, 2018 or (3) the termination of the EDA in accordance with its terms. Either party may terminate the EDA at any time upon written notification to the other party in accordance with the EDA, and upon such notification, the offering will terminate.

We agreed to pay JMP a commission of up to 3.0% of the gross sales price of any shares sold pursuant to the EDA. With the exception of expenses related to the shares, JMP will be responsible for all of its own costs and expenses incurred in connection with the offering.

During the nine months ended September 30, 2017, we issued 9,768,142 shares of our common stock pursuant to the EDA for aggregate net proceeds to us of \$14.9 million. As of September 30, 2017, \$19.8 million remained available under the EDA.

**9. Commitments**

In March 2017, the Company and CyDex Pharmaceuticals, Inc. (CyDex) entered into a License Agreement and a Supply Agreement. Under the terms of the License Agreement, CyDex has granted us an exclusive license to use CyDex's Captisol drug formulation system and related intellectual property in connection with the development and commercialization of ganaxolone in any and all therapeutic uses in humans, with some exceptions.

As consideration for this license, we paid an upfront fee which was recorded as research and development expense in the three months ended March 31, 2017, and are required to make additional payments in the future upon achievement of various specified clinical and regulatory milestones. We will also be required to pay royalties to CyDex on sales of ganaxolone, if successfully developed, in the low-to-mid single digits based on levels of annual net sales.

Under the terms of the Supply Agreement, we are required to purchase all of our requirements for Captisol with respect to ganaxolone from CyDex, and CyDex is required to supply us with Captisol for such purposes, subject to certain limitations.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," and or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our ability to develop and commercialize ganaxolone;
- status, timing and results of preclinical studies and clinical trials;
- enrollment in clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, or the attainment of clinical trial results that will be supportive of regulatory approvals;
- the potential benefits of ganaxolone;
- the timing of seeking regulatory approval of ganaxolone;
- our ability to obtain and maintain regulatory approval;
- our estimates of expenses and future revenue and profitability;
- our estimates regarding our capital requirements and our needs for additional financing;
- our plans to develop and market ganaxolone and the timing of our development programs;
- our estimates of the size of the potential markets for ganaxolone;
- our selection and licensing of ganaxolone;
- our ability to attract collaborators with acceptable development, regulatory and commercial expertise;
- the benefits to be derived from corporate collaborations, license agreements, and other collaborative or acquisition efforts, including those relating to the development and commercialization of ganaxolone;
- sources of revenue, including contributions from corporate collaborations, license agreements, and other collaborative efforts for the development and commercialization of products;
- our ability to create an effective sales and marketing infrastructure if we elect to market and sell ganaxolone directly;

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- the rate and degree of market acceptance of ganaxolone;
- the timing and amount of reimbursement for ganaxolone;
- the success of other competing therapies that may become available;
- the manufacturing capacity for ganaxolone;
- our intellectual property position;
- our ability to maintain and protect our intellectual property rights;
- our results of operations, financial condition, liquidity, prospects, and growth strategies;
- the industry in which we operate; and
- the trends that may affect the industry or us.

You should refer to Part II Item 1A. “Risk Factors” of this Quarterly Report on this Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The following *Management’s Discussion and Analysis of Financial Condition and Results of Operations* should be read in conjunction with: (i) the interim consolidated financial statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our annual financial statements for the year ended December 31, 2016 which are included in our Annual Report on Form 10-K filed with the SEC on March 13, 2017.

### **Overview**

We are a clinical stage biopharmaceutical company focused on developing and commercializing innovative therapeutics to treat epilepsy and neuropsychiatric disorders. Our clinical stage product candidate, ganaxolone, is a positive allosteric modulator of the GABA<sub>A</sub> receptor being developed in three different dose forms: intravenous (IV), oral capsule and liquid suspension. The multiple dose forms are intended to maximize the therapeutic range of ganaxolone for both adult and pediatric patient populations, in both acute and chronic care, and both in-patient and self-administered settings. Ganaxolone exhibits anti-seizure, anti-depression and anti-anxiety activity via its effects on synaptic and extrasynaptic GABA<sub>A</sub> receptors.

#### *CDKL5 deficiency disorder (CDD)*

In September 2017, we announced Phase 2 results in patients suffering from CDD. Patients in the CDD cohort of our ongoing Phase 2 open-label study in orphan pediatric epilepsies showed a median decrease of 43% (n=7) in 28-day seizure frequency from baseline in the ITT (intent-to-treat) population (primary endpoint). The median change from

baseline in seizure-free days in the ITT population (key secondary endpoint) was an increase of 78% (n=5; two subjects cannot be calculated due to 0 baseline seizure-free days). Four patients continue to receive ganaxolone; three of which have entered the one-year extension of the study and one of which is still receiving treatment within the 26-week treatment period. Ganaxolone was generally safe and well-tolerated with no serious adverse events. To date, there have been no adverse event reports of somnolence or dizziness and two children discontinued prior to completing the 26-week treatment due to lack of efficacy. We are planning to meet with regulatory agencies to discuss the clinical development plan with the goal of commencing a clinical study in 2018.

*Postpartum Depression (PPD)*

In June 2017, we initiated a Phase 2 double-blind, placebo-controlled clinical trial to evaluate the safety, efficacy and pharmacokinetics (PK) of ganaxolone IV in women diagnosed with severe PPD (Magnolia study). Patients randomized in the initial cohort(s) will undergo an infusion of either ganaxolone or placebo and will be followed for 30 days, with data expected in early 2018. Subsequent Magnolia study cohorts could include shorter- or higher-dose intravenous regimens alone or in sequential administration with oral ganaxolone. We are also initiating a Phase 2 study to evaluate the safety, tolerability and efficacy of ganaxolone oral capsules in moderate PPD patients (Amaryllis study).

*Status Epilepticus (SE)*

The Company is initiating its Phase 2 feasibility study with ganaxolone IV in patients with refractory status epilepticus (RSE). The Phase 2 trial is designed to treat patients in the SE treatment paradigm as second line when they have active brain function and potential for better outcomes. Data from this feasibility study is expected in 2018.

Our operations to date have consisted primarily of organizing and staffing our company and developing ganaxolone, including conducting preclinical testing and clinical trials. We have funded our operations primarily through sales of equity and debt securities. At September 30, 2017, we had cash, cash equivalents and investment balances of \$62.9 million. We have no products currently available for sale, have incurred operating losses since inception, have not generated any product sales revenue and have not achieved profitable operations. We incurred a net loss of \$14.2 million for the nine months ended September 30, 2017. Our accumulated deficit as of September 30, 2017 was \$140.0 million, and we expect to continue to incur substantial losses in future periods. We anticipate that our operating expenses will increase substantially as we continue to advance our clinical-stage product candidate, ganaxolone.

We anticipate that our expenses will increase substantially as we:

- conduct later stage clinical trials in CDD, PPD, SE and other targeted indications, which could include Lennox-Gastaut Syndrome (LGS), PCDH19 Pediatric Epilepsy (PCDH19-PE), Fragile X Syndrome (FXS) and others;
- continue the research, development and scale-up manufacturing capabilities to optimize products and dose forms for which we may obtain regulatory approval;
- conduct other preclinical and clinical studies to support the filing of New Drug Applications (NDAs) with the Food and Drug Administration (FDA) and other regulatory agencies in other countries;
- maintain, expand and protect our global intellectual property portfolio;
- hire additional clinical, manufacturing, and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development and potential future commercialization efforts.

We believe that our cash, cash equivalents and investments as of September 30, 2017, will enable us to fund our operating expenses and capital expenditure requirements into 2020. However, we will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of our planned research and development activities with respect to ganaxolone.

## **Financial Overview**

### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs incurred for the development of ganaxolone, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with Clinical Research Organizations (CROs) and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs associated with preclinical activities and regulatory operations.

We expense research and development costs as we incur them. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us. Research and development costs are net of state research and development tax credits which were sold to a third party for cash in the amount of \$0.4 million for the three and nine months ended September 30, 2017.

We will incur substantial costs beyond our present and planned clinical trials in order to file an NDA and Supplemental New Drug Applications (sNDAs) for ganaxolone for various clinical indications, and in each case, the nature, design, size and cost of further studies and trials will depend in large part on the outcome of preceding studies and trials and discussions with regulators. It is difficult to determine with certainty the costs and duration of our current or future clinical trials and preclinical studies, or if, when or to what extent we will generate revenue from the commercialization and sale of ganaxolone if we obtain regulatory approval. We may never succeed in achieving regulatory approval for ganaxolone. The duration, costs and timing of clinical trials and development of ganaxolone will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation.

In addition, the probability of success for ganaxolone will depend on numerous factors, including competition, manufacturing capability and commercial viability. See “Risk Factors.” Our commercial success depends upon attaining significant market acceptance of ganaxolone, if approved, among physicians, patients, healthcare payors and the medical community. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of ganaxolone, as well as an assessment of ganaxolone’s commercial potential.

### ***General and Administrative Expenses***

General and administrative expenses consist principally of salaries and related costs for executive and other administrative personnel and consultants, including stock-based compensation and travel expenses. Other general and administrative expenses include professional fees for legal, patent review, consulting and accounting services. General and administrative expenses are expensed when incurred. We expect that our general and administrative expenses will increase in the future as a result of new management and employee hiring and the scaling of our operations to support more advanced clinical trials.

### ***Interest Income***

Interest income consists principally of interest income earned on cash and cash equivalent and investment balances.

### ***Interest Expense***

Interest expense is primarily attributable to interest expense associated with our credit facility entered into in April 2014, as amended, which was paid in full and closed in July 2017.

### **Results of Operations**

#### ***Research and Development Expenses***

Research and development expenses decreased to \$2.6 million and \$9.0 million for the three and nine months ended September 30, 2017, respectively, as compared to \$4.8 million and \$17.6 million for the same periods in the prior year. The decreases were primarily due to a decrease of \$1.8 million and \$9.3 million for the three and nine month periods ended September 30, respectively, associated with our drug-resistant focal onset seizures program, which we discontinued in June 2016. Additionally, we sold \$0.4 million in state research and development tax credits which we used to offset research and development expenses. The decrease was partially offset by an increase of \$0.9 million for the nine-month period ended September 30, associated with our IV programs in PPD, for which a Phase 2 clinical trial was initiated in June 2017, and SE, for which we are initiating a Phase 2 clinical trial.

The primary drivers of our research and development expenditures have been in our drug-resistant focal onset seizures and IV programs. We incurred \$0.1 million and \$1.5 million in research and development expenses related to our preclinical and clinical activities associated with our drug-resistant focal onset seizures program in the three and nine months ended September 30, 2017, respectively, compared to \$1.9 million and \$10.8 million for the same periods in the prior year. We incurred \$1.3 million and \$3.3 million in research and development expenses related to our preclinical and clinical activities associated with our IV programs in PPD and SE in the three and nine months ended September 30, 2017, respectively, compared to \$1.4 million and \$2.4 million for the same periods in the prior year.

Prospectively, we do not expect to incur significant expenses for our focal onset seizure program as this program has been discontinued. We plan to focus our resources and near-term development efforts on other indications such as CDD, PPD and SE.

#### ***General and Administrative Expenses***

General and administrative expenses were \$1.6 million and \$5.1 million for the three and nine months ended September 30, 2017 as compared to similar expense amounts of \$1.5 million and \$4.7 million for the same periods in the prior year.

### **Liquidity and Capital Resources**

Since inception, we have incurred net losses and negative cash flows from our operations. We incurred a net loss of \$14.2 million for nine months ended September 30, 2017. Our cash used in operating activities was \$14.3 million for the nine months ended September 30, 2017 compared to \$18.7 million for the same period a year ago. Historically, we have financed our operations principally through the sale of common stock, preferred stock and convertible debt, and the use of term loans. At September 30, 2017, we had cash, cash equivalents and investment balances of \$62.9 million. During 2017, we received net proceeds of \$37.7 million through the sale of our common stock in connection with a secondary public offering and \$14.9 million through the sale of our common stock in connection with an Equity Distribution Agreement.

#### ***Credit Facility***

In 2014, we borrowed an aggregate of \$7.0 million in connection with a Loan and Security Agreement, as amended (LSA). In July 2017, we paid in full the entire outstanding term loans balance of \$3.5 million and accrued interest, with no penalty for prepayment. Through July 2017 and pursuant to the terms of the LSA, we were required to make monthly interest payments for all outstanding borrowings at an interest rate equal to the greater of (a) prime rate plus 3.25% or (b) 6.5% and monthly principal payments of 1/24th of our principal borrowings plus interest.



Interest expense related to the term loans was \$3 thousand and \$159 thousand for the three and nine months ended September 30, 2017. As of September 30, 2017, we had no accrued interest.

### **Cash Flows**

*Operating Activities.* Cash used in operating activities decreased to \$14.3 million for the nine months ended September 30, 2017 compared to \$18.7 million for the same period a year ago. The decrease was driven primarily by a decrease in our net loss of \$8.5 million, partially offset by a decrease in the change in operating assets and liabilities of \$4.1 million. The net decrease in the change in operating assets and liabilities was primarily due to upfront payments for planned clinical trials in our IV program, payment of corporate insurance premiums and the timing of payment obligations related to our drug supply in 2016.

*Investing Activities.* Cash used in investing activities for the nine months ended September 30, 2017 represents the purchase of \$24.9 million in U.S. Treasury securities and \$0.2 million purchases of equipment, offset by maturities of \$3.4 million in certificates of deposit. Cash provided by investing activities for the nine months ended September 30, 2016 represents maturities of \$4.2 million in certificates of deposit offset by the purchase of \$2.4 million in certificates of deposit and payments of \$0.6 million for equipment.

*Financing Activities.* Cash provided by financing activities was \$47.3 million for the nine months ended September 30, 2017 due to net proceeds of \$37.7 million in connection with equity issuances from a secondary public offering and \$14.9 million in connection with equity issuances from our Equity Distribution Agreement with JMP Securities LLC, offset by \$5.2 million in debt repayments. Cash used in financing activities for the nine months ended September 30, 2016 of \$1.3 million was due to \$1.2 million in debt repayments and \$0.2 million payment of public offering costs, offset by \$0.1 million received from the exercise of outstanding stock options.

### **Funding Requirements**

We have never been profitable since our inception, and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to increase in the near term as we fund our planned clinical trials for ganaxolone.

We believe that our cash, cash equivalents and investments as of September 30, 2017 will enable us to fund our operating expenses and capital expenditure requirements into 2020. However, we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a negative impact on our business, results of operations, and financial condition. Our future capital requirements will depend on many factors, including:

- the results of our preclinical studies and clinical trials;
- the development, formulation and commercialization activities related to ganaxolone;
- the scope, progress, results and costs of researching and developing ganaxolone or any other future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for ganaxolone or any other future product candidates;
- the cost of commercialization activities if ganaxolone or any other future product candidates are approved for sale, including marketing, sales and distribution costs;

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- the cost of manufacturing ganaxolone or any other future product candidates in preclinical studies, clinical trials and, if approved, in commercial sale;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- any product liability, infringement or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Please see “Risk Factors” for additional risks associated with our substantial capital requirements.

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

We do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

### **Discussion of Critical Accounting Policies and Significant Judgments and Estimates**

The preparation of financial statements in conformity with GAAP requires us to use judgment in making certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in our financial statements and accompanying notes. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require difficult, subjective and complex judgments by management in order to make estimates about the effect of matters that are inherently uncertain. During the nine months ended September 30, 2017, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2016, which we included in our Annual Report on Form 10-K and was filed with the SEC on March 13, 2017.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk**

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations.

We had cash, cash equivalents and investment balances of \$62.9 million at September 30, 2017, consisting primarily of funds in cash, money market accounts certificates of deposit and U.S. Treasury securities. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, we do not believe an immediate 1.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect a sudden change in market interest rates to affect materially our operating results or cash flows.

### **Item 4. Controls and Procedures**

#### **(a) Evaluation of Disclosure Controls and Procedures.**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2017. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and

procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2017, our disclosure controls and procedures were effective to ensure that the information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

**(b) Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(f) and 15d-15(f) of the Exchange Act that occurred during the quarter ended September 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II**  
**OTHER INFORMATION**

**Item 1. Legal Proceedings**

From time to time, we may become subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results or financial condition.

**Item 1A. Risk Factors**

*We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.*

We commenced operations in 2003 and our operations to date have been limited to conducting product development activities for ganaxolone and performing research and development with respect to our clinical and preclinical programs. In addition, as a clinical stage biopharmaceutical company, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Nor have we demonstrated an ability to obtain regulatory approval to commercialize any of our product candidates. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception, including a net loss of \$14.2 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of \$140.0 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our losses have resulted principally from costs incurred in our research and development activities. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our research, development and commercialization activities, including the clinical development and planned commercialization of our product candidate, ganaxolone. In addition, if we obtain regulatory approval of ganaxolone, we may incur significant sales and marketing expenses. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or whether or when we will become profitable, if ever.

*We have not generated any revenue to date from product sales. We may never achieve or sustain profitability, which could depress the market price of our common stock, and could cause you to lose all or a part of your investment.*

To date, we have no products approved for commercial sale and have not generated any revenue from sales of any of our product candidates, and we do not know when, or if, we will generate revenues in the future. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully gain regulatory approval and commercialize ganaxolone or other product candidates that we may develop, in-license or acquire in the future. Even if we obtain regulatory approval for ganaxolone, we do not know when we will generate revenue from product sales, if at all. Our ability to generate revenue from product sales from ganaxolone or any other future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including enrollment of study participants, completion of the necessary clinical trials and attainment of clinical trial results that will support regulatory approvals;
- complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

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- make or have made commercial quantities of our products at acceptable cost levels;
- develop a commercial organization capable of manufacturing, selling, marketing and distributing any products we intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable partners to help us market, sell and distribute our approved products in other markets; and
- obtain adequate pricing, coverage and reimbursement from third parties, including government and private payers.

In addition, because of the numerous risks and uncertainties associated with product development, including that ganaxolone may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for ganaxolone, we anticipate incurring significant costs associated with commercializing ganaxolone.

Even if we are able to generate revenue from the sale of ganaxolone or any future commercial products, we may not become profitable and will need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, and we are not successful in obtaining additional funding, then we may be unable to continue our operations at planned levels, or at all, which would likely materially and adversely affect the market price of our common stock.

***We will require additional capital to fund our operations and if we fail to obtain necessary financing, we may be unable to complete the development and commercialization of ganaxolone.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical and regulatory development of ganaxolone, if approved, and commercialize ganaxolone. We will require additional capital for the further development and potential commercialization of ganaxolone and may also need to raise additional funds sooner should we choose to accelerate development of ganaxolone. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our cash, cash equivalents and investments as of September 30, 2017, will enable us to fund our operating expenses and capital expenditure requirements into 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for ganaxolone or any other future product candidates;
- clinical development plans we establish for ganaxolone and any other future product candidates;
- obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- number and characteristics of product candidates that we discover or in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;

- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised. Failure to progress our product development or commercialization of ganaxolone as anticipated will have a negative effect on our business, future prospects and ability to obtain further financing on acceptable terms, if at all, and the value of the enterprise.

***Raising additional capital could dilute our stockholders, restrict our operations or require us to relinquish rights to ganaxolone or any other future product candidates.***

Until we can generate substantial revenue from product sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include liens or restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to ganaxolone or any other future product candidates in particular countries, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market ganaxolone or any other future product candidates that we would otherwise prefer to develop and market ourselves.

***We intend to expend our limited resources to pursue our sole clinical stage product candidate, ganaxolone, and may fail to capitalize on other indications, technologies or product candidates that may be more profitable or for which there may be a greater likelihood of success.***

Because we have limited financial and managerial resources, we are focusing on research programs relating to ganaxolone, which concentrates the risk of product failure in the event ganaxolone proves to be ineffective or inadequate for clinical development or commercialization in this indication. As a result, we may forego or delay pursuit of opportunities for other technologies or product candidates that later could prove to have greater commercial potential. We may be unable to capitalize on viable commercial products or profitable market opportunities as a result of our resource allocation decisions. Our spending on proprietary research and development programs relating to ganaxolone may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for ganaxolone, we may relinquish valuable rights to ganaxolone through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to ganaxolone.

#### **Risks Related to Our Business and Development of Our Product**

***Our future success is dependent on the successful clinical development, regulatory approval and commercialization of ganaxolone, which is currently undergoing two clinical trials and will require significant capital resources and years of additional clinical development effort.***

We do not have any products that have gained regulatory approval. Currently, our only clinical stage product candidate is ganaxolone. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize ganaxolone in a timely manner. We cannot commercialize ganaxolone in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize ganaxolone outside of the United States without obtaining regulatory approval

from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of ganaxolone for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two adequate and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that ganaxolone is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if ganaxolone were to obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations, such as restrictions as to specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for ganaxolone in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other product candidate that we may in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for ganaxolone, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payers. If we are unable to successfully commercialize ganaxolone, we may not be able to earn sufficient revenue to continue our business.

***Because the results of preclinical studies or earlier clinical trials are not necessarily predictive of future results, ganaxolone may not have favorable results in later preclinical studies or clinical trials or receive regulatory approval.***

Success in preclinical studies and early clinical trials does not ensure that later trials will generate adequate data to demonstrate the efficacy and safety of ganaxolone. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in preclinical studies and clinical trials, even after seeing promising results in earlier studies and trials. For example, while ganaxolone showed statistical separation from placebo in a Phase 2 study in adjunctive treatment of adults with focal onset seizures, ganaxolone failed to show a similar statistical separation in a Phase 3 study for the same indication. As a result, we discontinued our program in adult focal onset seizures and to focus our efforts on advancing ganaxolone in postpartum depression, status epilepticus, and pediatric orphan indications. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market ganaxolone in any particular jurisdiction or indication. If clinical trials underway or conducted in the future do not produce favorable results, our ability to achieve regulatory approval for ganaxolone may be adversely impacted.

***The therapeutic efficacy and safety of ganaxolone are unproven, and we may not be able to successfully develop and commercialize ganaxolone in the future.***

Ganaxolone is a novel compound and its potential therapeutic benefit is unproven. Our ability to generate revenue from ganaxolone, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our successful development and commercialization after regulatory approval, which is subject to many potential risks and may not occur. Ganaxolone may interact with human biological systems in unforeseen, ineffective or harmful ways. If ganaxolone is associated with undesirable side effects or has characteristics that are unexpected, we may need to abandon its development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating the target indications for ganaxolone have later been found to cause side effects that prevented further development of the compound. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third-party licensing or collaboration transactions with respect to, or successfully commercialize, ganaxolone, in which case we will not achieve profitability and the value of our stock may decline.

***Clinical development of product candidates involves a lengthy and expensive process with an uncertain outcome.***

Clinical testing is expensive, can take many years to complete, and is inherently uncertain as to outcome. Failure can occur at any time during the clinical trial process.

We may experience delays in our ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA or other foreign regulatory authorities will not put clinical trials of ganaxolone on clinical hold

now or in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable study subjects to participate in a trial;
- delay or failure in study subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for competing product candidates with the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results or results that are inconsistent with earlier results;
- feedback from the FDA, IRBs, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for the trial;
- decision by the FDA, an IRB, a comparable foreign regulatory authority, or us, or recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects or adverse events;
- failure of a product candidate to demonstrate any benefit;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials;



- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties;
- political developments that affect our ability to develop and obtain approval for ganaxolone, or license rights to develop and obtain approval for ganaxolone, in a foreign country; or
- changes in governmental regulations or administrative actions.

Study subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the subject population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain subject consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved or product candidates that may be studied in competing clinical trials for the indications we are investigating. Some of our clinical trials are directed at small patient populations. Patient enrollment in these studies could be particularly challenging. In the past, we have experienced delays in enrolling patients in studies directed at small patient populations. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

If we experience delays in the completion of any clinical trial of ganaxolone, the commercial prospects of ganaxolone may be harmed, and our ability to generate product revenue from ganaxolone, if approved, will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our development and approval process for ganaxolone and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of ganaxolone.

***Ganaxolone may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.***

Undesirable side effects caused by ganaxolone could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Although ganaxolone has generally been well tolerated by subjects in our earlier-stage clinical trials, in some cases there were side effects, and some of the side effects were severe. Specifically, in our most recently completed clinical trial, where ganaxolone was administered as an adjunctive to standard therapy in adult subjects with focal onset seizures, the most frequent side effects (those reported in greater than 5% of ganaxolone subjects) were dizziness, fatigue and somnolence (or drowsiness). More side effects of the Central Nervous System (CNS) were categorized as severe as compared to side effects of other body systems.

If these side effects are reported in future clinical trials, or if other safety or toxicity issues are reported in our future clinical trials, we may not receive approval to market ganaxolone, which could prevent us from ever generating revenue or achieving profitability. Furthermore, although we are currently developing ganaxolone for three indications, negative safety findings in any one indication could force us to delay or discontinue development in other indications. Results of our clinical trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development, or deny approval, of ganaxolone for any or all targeted indications. Drug-related side effects could affect study subject recruitment or the ability of enrolled subjects to complete our future clinical trials and may result in potential product liability claims.

Additionally, if ganaxolone receives marketing approval, and we or others later identify undesirable side effects caused by ganaxolone, a number of potentially significant negative consequences could result, including:

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- we may be forced to suspend marketing of ganaxolone;
- regulatory authorities may withdraw their approvals of ganaxolone;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of ganaxolone;
- we may be required to conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ganaxolone, if approved.

### ***Even if ganaxolone receives regulatory approval, we may still face regulatory difficulties.***

Even if we obtain regulatory approval for ganaxolone, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of ganaxolone will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If new safety information becomes available after approval of ganaxolone, the FDA or comparable foreign regulatory authorities may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy (REMS) or similar strategy, impose significant restrictions on ganaxolone's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for ganaxolone, if it achieves marketing approval, may include restrictions on use.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (cGMP) and other regulations. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, ganaxolone or the manufacturing facilities for ganaxolone fail to comply with applicable regulatory requirements, a regulatory authority may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;

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- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit or preclude our ability to commercialize ganaxolone and generate revenue.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of ganaxolone. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by, among others, the FDA, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, promoting ganaxolone for unapproved indications can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increasing focus and scrutiny has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and/or investigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

### ***Failure to obtain regulatory approval in international jurisdictions would prevent ganaxolone from being marketed in these jurisdictions.***

In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, many countries outside the United States require that a product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of ganaxolone by regulatory authorities in

the European Union or another country or jurisdiction, the commercial prospects of ganaxolone may be significantly diminished and our business prospects could decline.

***We may not be able to obtain orphan drug exclusivity for ganaxolone or any other product candidates for which we seek it, which could limit the potential profitability of ganaxolone or such other product candidates.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for an indication for which it receives the designation, then the product is entitled to a period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication for the exclusivity period except in limited situations. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

We have received orphan drug designation for treating CDD, PCDH19-PE, FXS and SE with ganaxolone and expect that we may in the future pursue orphan drug designations for ganaxolone for one or more additional indications. However, obtaining an orphan drug designation can be difficult and we may not be successful in doing so for additional ganaxolone indications or any future product candidates. Even if we were to obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

***Our business and operations would suffer in the event of computer system failures.***

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding subjects enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of data relating to completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and cause us to incur significant additional costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of ganaxolone could be delayed.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce ganaxolone. Our ability to obtain clinical supplies of ganaxolone could be disrupted

if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

#### **Risks Related to the Commercialization of Our Product**

***Our commercial success depends upon attaining significant market acceptance of ganaxolone, if approved, among physicians, patients, government and private payers and others in the medical community.***

Even if ganaxolone receives regulatory approval, it may not gain market acceptance among physicians, patients, government and private payers, or others in the medical community. Market acceptance of ganaxolone, if we receive approval, depends on a number of factors, including the:

- efficacy and safety of ganaxolone, or ganaxolone administered with other drugs, each as demonstrated in clinical trials and post-marketing experience;
- clinical indications for which ganaxolone is approved;
- acceptance by physicians and patients of ganaxolone as a safe and effective treatment;
- potential and perceived advantages of ganaxolone over alternative treatments;
- safety of ganaxolone seen in a broader patient group, including its use outside the approved indications should physicians choose to prescribe for such uses;
- prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of ganaxolone as well as competitive products;
- cost of treatment in relation to alternative treatments;
- availability of coverage and adequate reimbursement and pricing by government and private payers;
- relative convenience and ease of administration; and
- effectiveness of our sales and marketing efforts.

If ganaxolone is approved but fails to achieve market acceptance among physicians, patients, government or private payers or others in the medical community, or the products or product candidates that are being administered with ganaxolone are restricted, withdrawn or recalled, or fail to be approved, as the case may be, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell ganaxolone, we may be unable to generate any revenue.***

We do not currently have an organization for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We

will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies. To the extent we rely on third parties to commercialize ganaxolone, if approved, we may have little or no control over the marketing and sales efforts of such third parties, and our revenues from product sales may be lower than if we had commercialized ganaxolone ourselves.

***A variety of risks associated with marketing ganaxolone internationally could materially adversely affect our business.***

We plan to seek regulatory approval for ganaxolone outside of the United States, and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

***Even if we are able to commercialize ganaxolone, it may not receive coverage and adequate reimbursement from third-party payers, which could harm our business.***

Our ability to commercialize ganaxolone successfully will depend, in part, on the extent to which coverage and adequate reimbursement for ganaxolone and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the United States healthcare industry and elsewhere is cost containment.

Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. Third-party payers may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering ganaxolone for those patients. We cannot be sure that coverage and adequate reimbursement will be available for ganaxolone and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, ganaxolone, if we obtain marketing approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize ganaxolone even if we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to obtain coverage and profitable reimbursement rates from both government-funded and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to ganaxolone, and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing ganaxolone. Some of these competitive products and therapies are based on scientific approaches that are the same as, or similar to, our approach, and others are based on entirely different approaches. For example, there are several companies developing product candidates that target the same GABA<sub>A</sub> neuroreceptor that we are targeting or that are testing product candidates in the same indications that we are testing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Ganaxolone is presently being developed primarily as a neuropsychiatric therapeutic. There are a variety of marketed therapies available for these patients.

Specifically, there are more than 15 approved AEDs available in the United States and worldwide, including the generic products levetiracetam, lamotrigine, carbamazepine, oxcarbazepine, valproic acid and topiramate. Recent market entrants include branded products developed by Lundbeck, UCB, Eisai, and Sunovion Pharmaceuticals. Additionally, there are several drugs in development for the treatment of pediatric genetic epilepsies and behavioral and mental health conditions associated with FXS, including compounds being developed by GW Pharmaceuticals, Zogenix, Sunovion Pharmaceuticals, Zynerba, Alcobra and Neuren Pharmaceuticals. Sage Therapeutics is developing molecules with a similar mechanism of action as ganaxolone for treatment of SE and PPD.

Many of the approved drugs are well established therapies or products and are widely accepted by physicians, patients and third-party payers. Insurers and other third-party payers may also encourage the use of generic products.

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These factors may make it difficult for us to achieve market acceptance at desired levels or in a timely manner to ensure viability of our business.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources.

As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize ganaxolone. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render ganaxolone obsolete or non-competitive before we can recover the expenses of ganaxolone's development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

### ***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of ganaxolone or other product candidates that we may develop.***

We face an inherent risk of product liability exposure related to the testing of ganaxolone by us or our investigators in human clinical trials and will face an even greater risk if ganaxolone receives regulatory approval and we subsequently commercialize it. Product liability claims may be brought against us by study subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling ganaxolone. If we cannot successfully defend ourselves against claims that ganaxolone caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, for example:

- decreased demand for ganaxolone;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize ganaxolone; and
- increased scrutiny and potential investigation by, among others, the FDA, the DOJ, the Office of Inspector General of the HHS, state attorneys general, members of Congress and the public.

We currently have product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our product liability



insurance coverage to include the sale of commercial products if we obtain marketing approval for ganaxolone, but we may be unable to obtain commercially reasonable product liability insurance for ganaxolone, if approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

#### **Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize ganaxolone.***

We rely on third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific requirements and standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices (GLP) and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and Good Clinical Practices (GCP), which are international requirements meant to protect the rights and health of subjects that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for ganaxolone and any future product candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize ganaxolone. As a result, our results of operations and the commercial prospects for ganaxolone would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***If we lose our relationships with CROs, our drug development efforts could be delayed.***

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs generally have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us, or research projects pursuant to such agreements, if, in the reasonable opinion of the relevant CRO, the safety of the subjects participating in our clinical trials warrants such termination. These agreements or research projects may also be terminated if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

***Our experience manufacturing ganaxolone is limited to the needs of our preclinical studies and clinical trials. We have no experience manufacturing ganaxolone on a commercial scale and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of ganaxolone as well as on third parties for our supply chain, and if we experience problems with any such third parties, the manufacturing of ganaxolone could be delayed.***

We do not own or operate facilities for the manufacture of ganaxolone. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on contract manufacturing organizations (CMOs) for the chemical manufacture of active pharmaceutical ingredients for ganaxolone and other CMOs for the production of the ganaxolone nanoparticulate formulation into capsules, liquid suspension and IV. To meet our projected needs for preclinical and clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for ganaxolone. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms, in a timely manner or at all, we may not be able to complete development of ganaxolone, or market or distribute ganaxolone.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured ganaxolone ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture ganaxolone or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities would require that ganaxolone and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of ganaxolone in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of ganaxolone. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for ganaxolone previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of ganaxolone, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of ganaxolone or its key materials for an ongoing preclinical study or clinical trial could considerably delay completion of our preclinical study or clinical trial, product testing and potential regulatory approval of ganaxolone. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for ganaxolone, the commercial launch of ganaxolone would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of ganaxolone.

***We may elect to enter into licensing or collaboration agreements to partner ganaxolone in territories currently retained by us. Our dependence on such relationships may adversely affect our business.***

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize ganaxolone. In the event we grant exclusive rights to such partners, we would be precluded from potential commercialization of ganaxolone within the territories in which we have a partner. In addition, any termination of our collaboration agreements will terminate the funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs.

Our commercialization strategy for ganaxolone may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of ganaxolone in the territories in which we seek to partner. Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize ganaxolone. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our potential future collaborators could delay or terminate their agreements, and as a result ganaxolone may never be successfully commercialized.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that ganaxolone receives less attention or resources than we would like, or they may be terminated altogether. Any such actions by our potential future collaborators may adversely affect our business prospects and ability to earn revenue. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of ganaxolone or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

***Government funding for certain of our programs adds uncertainty to our research efforts with respect to those programs and may impose requirements that increase the costs of commercialization and production of product candidates developed under those government-funded programs.***

Our preclinical studies and clinical trials to evaluate ganaxolone in FXS patients have been conducted with the MIND Institute at the University of California, Davis which receives funding from the United States Department of Defense (DoD) for such studies and trials. In addition, our preclinical studies and clinical trials to evaluate ganaxolone in patients suffering from posttraumatic stress disorder (PTSD) have been primarily conducted by the United States Department of Veterans Affairs, which also receives funding from the DoD. Programs funded by the United States government and its agencies, including the DoD, include provisions that confer on the government substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;

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- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose United States manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor from doing future business with the government; and
- control and potentially prohibit the export of products.

We may not have the right to prohibit the United States government from using or allowing others to use certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the United States government. The United States government generally obtains the right to royalty-free use of technologies that are developed under United States government contracts.

In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential contract liability and to termination of our contracts.

Changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the development of ganaxolone in patients suffering from certain FXS-associated behavioral symptoms. Although we intend to fund a portion of our development programs for ganaxolone in patients with FXS, any reduction or delay in DoD funding to our collaborators may force us to suspend or terminate these programs or seek alternative funding, which may not be available on non-dilutive terms, terms favorable to us or at all.

***If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. We cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future

environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

#### **Risks Related to Regulatory Compliance**

***Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize ganaxolone and affect the prices we may obtain.***

The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of ganaxolone, restrict or regulate post-approval activities and affect our ability to successfully sell ganaxolone, if we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare and Medicaid Services, the agency that runs the Medicare program, also has the authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the Medicare Modernization Act and Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (Affordable Care Act), a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms was signed into law. The Affordable Care Act expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price (AMP) to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100.0% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the effect of the Affordable Care Act, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If we ever obtain regulatory approval and commercialization of ganaxolone, these new laws may result in additional reductions in Medicare and other healthcare funding, which could

have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of ganaxolone may be.

In the United States, the European Union and other potentially significant markets for ganaxolone, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for ganaxolone in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in ganaxolone even if ganaxolone obtains marketing approval.

***Laws and regulations governing international operations may preclude us from developing, manufacturing and selling product candidates outside of the United States and require us to develop and implement costly compliance programs.***

As we seek to expand our operations outside of the United States, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act (FCPA) prohibits any United States individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain foreign nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing,

manufacturing, or selling ganaxolone outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the United States government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions.

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

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our operations (including our marketing, promotion, educational programs, pricing, and relationships with healthcare providers or other entities, among other things) and expose us to areas of risk including the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or Children's Health Insurance Program, to report annually to HHS information related to payments and other transfers of value to physicians and teaching hospitals, and

ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and

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

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

#### **Risks Related to Our Intellectual Property**

*If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.*

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

With respect to patent rights, we do not know whether any of our granted or issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific



literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensors' patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned or controlled by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell ganaxolone, and to use our related technologies. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to ganaxolone, including interference or derivation proceedings before the United States Patent and Trademark Office (USPTO). Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing ganaxolone. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing ganaxolone. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing ganaxolone or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

While ganaxolone is in preclinical studies and clinical trials, we believe that the use of ganaxolone in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the

United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As ganaxolone progresses toward commercialization, the possibility of a patent infringement claim against us increases. While ganaxolone itself is off patent, we attempt to ensure that our solid and liquid nanoparticulate formulation of ganaxolone and the methods we employ to manufacture ganaxolone do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

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

Filing, prosecuting and defending patents on ganaxolone and any future product candidates throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries, particularly those relating to biopharmaceuticals, do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, novel formulations and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of our patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

We may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.***

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as ganaxolone, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

***Changes in patent laws, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate patent rights, which could adversely affect our competitive position.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

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

Some of our employees were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to

commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds or ganaxolone formulations that are similar to our ganaxolone formulations but that are not covered by the claims of the patents that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or control may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

**Risks Related to Employee Matters and Managing Growth**

***Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.***

We are highly dependent upon Christopher M. Cashman, our Chief Executive Officer, Edward F. Smith, our Chief Financial Officer and Lorianne Masuoka, MD, our Chief Medical Officer. The employment agreements we have with the persons named above do not prevent such persons from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of September 30, 2017, we had one part-time and 14 full-time employees. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, sales, marketing, financial and other resources. In addition, it may become more cost effective to bring in house certain resources currently outsourced to consultants and other third-parties. Our management,

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personnel and systems currently in place may not be adequate to support our future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize ganaxolone, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

***If we are unable to attract and retain highly qualified employees, and other personnel, advisors and consultants with scientific, technical and managerial expertise, we may not be able to grow effectively.***

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees, consultants and other third-parties. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel, advisors and consultants. The competition for qualified personnel in the pharmaceutical field is significant and, as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

***We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.***

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We have no experience with acquiring other companies, products or product candidates, and limited experience with forming strategic alliances and collaborations. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliance or collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or equity securities as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or

volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees (Code of Conduct) but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

#### **Risks Related to Ownership of Our Common Stock**

***The market price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this “Risk Factors” section, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of ganaxolone or product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;

- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, The NASDAQ Global Market and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse impact on the market price of our common stock.

***We may be subject to securities litigation, which is expensive and could divert our management’s attention.***

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

***Insiders have substantial influence over us and could delay or prevent a change in corporate control.***

We estimate that our executive officers, directors, and holders of 5% or more of our capital stock collectively beneficially own approximately 46.6% of our voting stock. This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might negatively affect the prevailing market price for our common stock.

***We are an “emerging growth company” and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31. If we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of United States generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

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

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of September 30, 2017 we had outstanding a total of 40,431,096 shares of common stock. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and either the registration of such shares under the Securities Act or the application of exemptions from such registration with respect to any sales such as Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.



***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of equity or equity-linked securities, together with the exercise of stock options, warrants outstanding or granted in the future and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers. As of September 30, 2017, there were no shares of our common stock available for future grant under our 2005 Stock Option and Incentive Plan, as amended. The number of shares of our common stock available for future grant under our 2014 Equity Incentive Plan, as Amended, was 1,258,825 as of September 30, 2017. Future equity incentive grants and issuances of common stock under our equity incentive plans may have an adverse effect on the market price of our common stock.

***We have broad discretion in the use of our cash reserves and may not use them effectively.***

Our management has broad discretion over the management of our operations and cash resources and could deploy our resources in ways that do not improve our business, including our ganaxolone clinical development programs, or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the market price of our common stock to decline and delay the development of ganaxolone.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that:

- permit our board of directors to issue up to 25,000,000 shares of preferred stock, with any rights, preferences and privileges as it may designate;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- establish a classified board of directors such that only one of three classes of directors is elected each year;
- provide that directors can only be removed for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

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- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the chairperson of the board of directors, the chief executive officer or the board of directors.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15.0% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***We are required to meet the NASDAQ Stock Market's continued listing requirements and other NASDAQ rules, or we may risk delisting. Delisting could negatively affect the price of our common stock, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock.***

We are required to meet the continued listing requirements of the NASDAQ Stock Market and other NASDAQ rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of \$1.00 per share. If we do not meet these continued listing requirements, our common stock could be delisted. Delisting from the NASDAQ Stock Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the NASDAQ Stock Market in the future, would be listed on a national securities exchange, a national quotation service, the over-the-counter markets or the pink sheets. Delisting from the NASDAQ Stock Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, cause us to lose eligibility to register the sale or resale of our shares on Form S-3 and the automatic exemption from registration under state securities laws for exchange-listed securities, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

### **Item 3. Defaults upon Senior Securities**

None.

### **Item 4. Mine Safety Disclosures**

Not applicable.

## Item 5. Other Information

### Item 1.01 of Form 8-K disclosure

On October 31, 2017, the Company entered into an Equity Distribution Agreement (the “Agreement”) with JMP Securities, LLC (“JMP”), relating to the sale to the sale of up to \$50,000,000 of shares of the Company’s common stock, par value \$.001 per share (the “Common Stock”) with JMP acting as sales agent.

Sales of Common Stock, if any, may be made in sales deemed to be “at the market offerings” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on or through the NASDAQ Global Market, the existing trading market for the Common Stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law. JMP Securities will use commercially reasonable efforts to sell on the Company’s behalf all of the shares of Common Stock requested to be sold by the Company, consistent with its normal trading and sales practices, on mutually agreed terms between JMP Securities and the Company. Under the Agreement, JMP will be entitled to a commission of up to 3.0% of the gross proceeds for shares of Common Stock sold.

A copy of the Agreement is attached as Exhibit 1.1 to this quarterly report on Form 10-Q and incorporated herein by reference. The description of the Agreement is a summary only and is qualified in its entirety by reference to Exhibit 1.1.

## Item 6. Exhibits

<b>Exhibit Number</b>	<b>Exhibit Description</b>
1.1	<a href="#">Equity Distribution Agreement dated as of October 31, 2017 between the Company and JMP Securities LLC (filed herewith).</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act (filed herewith).</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act (filed herewith).</a>
32.1	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer (filed herewith).</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

**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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<hr/> <i>/s/ Christopher M. Cashman</i> Christopher M. Cashman	President and Chief Executive Officer (principal executive officer) and Director	October 31, 2017
<hr/> <i>/s/ Edward F. Smith</i> Edward F. Smith	Chief Financial Officer and Treasurer (principal financial and accounting officer)	October 31, 2017

MARINUS PHARMACEUTICALS, INC.

\$50,000,000

Shares of Common Stock

EQUITY DISTRIBUTION AGREEMENT

Dated: October 31, 2017

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MARINUS PHARMACEUTICALS, INC.

\$50,000,000

Shares of Common Stock

EQUITY DISTRIBUTION AGREEMENT

October 31, 2017

JMP Securities LLC  
600 Montgomery Street, Suite 1100  
San Francisco, California 94111

Ladies and Gentlemen:

Marinus Pharmaceuticals, Inc., a Delaware corporation (the “Company”) confirms its agreement (this “Agreement”) with JMP Securities LLC (the “Placement Agent”), as follows:

**SECTION 1. Description of Securities.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Placement Agent, acting as agent and/or principal, up to \$50,000,000 of shares (the “Securities”) of the Company’s common stock, par value \$0.001 per share (the “Common Stock”). Notwithstanding anything to the contrary contained herein, except as set forth in a Placement Notice (as defined below) the parties hereto agree that compliance with the limitations set forth in this Section 1 on the number of the Securities issued and sold under this Agreement shall be the sole responsibility of the Company, and the Placement Agent shall have no obligation in connection with such compliance. The issuance and sale of the Securities through the Placement Agent will be effected pursuant to the Registration Statement (as defined below) filed by the Company and declared effective by the Securities and Exchange Commission (the “Commission”), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to offer, sell or issue the Securities.

The Company shall file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the “Securities Act”), with the Commission a registration statement on Form S-3, including a base prospectus and a prospectus relating to the Securities to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the “Exchange Act”). The Company will promptly furnish to the Placement Agent, for use by the Placement Agent, copies of the prospectus included as part of such registration statement, and a prospectus supplement (the “Prospectus Supplement”), if any, relating to the Securities. Except where the context otherwise requires, such registration statement, as amended when it became effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act (the “Rule 430B Information”), is herein called the “Registration Statement.” The prospectus relating to the Securities, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the

Commission pursuant to Rule 424(b) under the Securities Act is herein called the “Prospectus.” Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. Any reference herein to financial statements and schedules and other information that is “contained,” “included” or “stated” in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be. Any reference herein to the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to the Commission’s Electronic Data Gathering, Analysis and Retrieval system (“EDGAR”); all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433 under the Securities Act, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR.

**SECTION 2. Placements.** Each time that the Company wishes to issue and sell the Securities hereunder (each, a “Placement”), it will notify the Placement Agent by email notice (or other method mutually agreed to in writing by the parties) containing the parameters in accordance with which it desires the Securities to be sold, which shall at a minimum include the number of Securities to be issued (the “Placement Securities”), the time period during which sales are requested to be made, any limitation on the number of Securities that may be sold in any one day and any minimum price below which sales may not be made (a “Placement Notice”), a form of which containing such minimum sales parameters necessary is attached hereto as Exhibit A. The Placement Notice shall originate from any of the individuals from the Company set forth on Exhibit B (with a copy to each of the other individuals from the Company listed on such exhibit), and shall be addressed to each of the individuals from the Placement Agent set forth on Exhibit B, as such Exhibit B may be amended from time to time. If the Placement Agent wishes to accept such proposed terms included in the Placement Notice (which it may decline to do so for any reason in its sole discretion) or, following discussion with the Company, wishes to accept amended terms, the Placement Agent will, prior to 4:30 p.m. (eastern time) on the Business Day (as defined below) following the Business Day on which such Placement Notice is delivered to the Placement Agent, issue to the Company a notice by email (or other method mutually agreed to in writing by the parties) addressed to all of the individuals from the Company and the Placement Agent set forth on Exhibit B setting forth the terms that the Placement Agent is willing to accept. Where the terms provided in the Placement Notice are amended as provided for in the immediately preceding sentence, such terms will not be binding on the Company or the Placement Agent until the Company delivers to the Placement Agent an acceptance by email (or other method mutually agreed to in writing by the parties) of all of the terms of such Placement Notice, as amended (the “Acceptance”), which email shall be addressed to all of the individuals from the Company and the Placement Agent set forth on Exhibit B. The Placement Notice (as amended by the corresponding Acceptance, if applicable) shall be effective upon receipt by the Company of the Placement Agent’s acceptance of the terms of the Placement Notice or upon receipt by the Placement Agent of the Company’s Acceptance, as the case may be, unless and until (i) the entire amount of the Placement Securities have been sold, (ii) in accordance with the Placement Notice requirements set forth in the second sentence of this paragraph, the Company terminates the Placement Notice, (iii) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, (iv) this Agreement has been terminated under the provisions of Section 9 or Section 12 or (v) either party shall have suspended the sale of the Placement Securities in accordance with Section 4 below. The amount of any discount,



commission or other compensation to be paid by the Company to the Placement Agent in connection with the sale of the Placement Securities shall be calculated in accordance with the terms set forth in Exhibit C.

It is expressly acknowledged and agreed that neither the Company nor the Placement Agent will have any obligation whatsoever with respect to a Placement or any Placement Securities unless and until the Company delivers a Placement Notice to the Placement Agent and either (i) the Placement Agent accepts the terms of such Placement Notice or (ii) where the terms of such Placement Notice are amended, the Company accepts such amended terms by means of an Acceptance pursuant to the terms set forth above and the Acceptance has been received by the Placement Agent, and then only upon the terms specified in the Placement Notice (as amended by the corresponding Acceptance, if applicable) and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice (as amended by the corresponding Acceptance, if applicable), the terms of the Placement Notice (as amended by the corresponding Acceptance, if applicable) will control. The term "Business Day" means each Monday, Tuesday, Wednesday, Thursday or Friday that is not a day on which banking institutions in New York are generally authorized or obligated by law or executive order to close.

**SECTION 3. Sale of Placement Securities by the Placement Agent.** Subject to the provisions of Section 6(a), the Placement Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Placement Securities up to the amount specified, and otherwise in accordance with the terms of such Placement Notice (as amended by the corresponding Acceptance, if applicable). The Placement Agent will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Securities hereunder setting forth the number of Placement Securities sold on such day, the compensation payable by the Company to the Placement Agent pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Placement Agent (as set forth in Section 6(b)) from the gross proceeds that it receives from such sales). Subject to the terms of the Placement Notice (as amended by the corresponding Acceptance, if applicable), the Placement Agent may sell Placement Securities by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on the NASDAQ Global Market (the "NASDAQ"), on any other existing trading market for the Common Stock or to or through a market maker. If specified in a Placement Notice (as amended by the corresponding Acceptance, if applicable), the Placement Agent may also sell Placement Securities by any other method permitted by law, including but not limited to in privately negotiated transactions. For the purposes hereof, "Trading Day" means any day on which shares of Common Stock are purchased and sold on the principal market on which the Common Stock is listed or quoted and during which there has been no market disruption of, unscheduled closing of or suspension of trading on such principal market.

**SECTION 4. Suspension of Sales.** The Company or the Placement Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Exhibit B, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Exhibit B), suspend any sale of Placement Securities; provided, however, that such suspension shall not affect or impair either party's obligations with respect to any Placement Securities sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this Section 4 shall be effective against the other unless it is made to all of the individuals of such other party named on Exhibit B hereto, as such Exhibit may be amended from time to time.

## SECTION 5. Representations and Warranties.

(a) Representations and Warranties by the Company. The Company represents and warrants to the Placement Agent as of the date hereof and as of each Representation Date (as defined herein) on which a certificate is required to be delivered pursuant to Section 7(o) of this Agreement and as of the time of each sale of any Securities pursuant to this Agreement (the "Applicable Time"), and agrees with the Placement Agent, as follows:

(1) *Compliance with Registration Requirements.* The Securities have been duly registered under the Securities Act pursuant to the Registration Statement. The Registration Statement has become effective under the Securities Act, or, with respect to any registration statement to be filed to register the offer and sale of the Securities pursuant to Rule 462(b) under the Securities Act, including the documents incorporated by reference therein and the Rule 430B Information, (a "Rule 462(b) Registration Statement"), will be filed with the Commission and become effective under the Securities Act no later than 10:00 P.M. New York City time on the date of determination of the public offering price for the Securities, and no stop order preventing or suspending the use of any base prospectus, the Prospectus Supplement, the Prospectus or any Permitted Free Writing Prospectus (as defined below), or the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated by the Commission, and any request on the part of the Commission for additional information has been complied with.

At the respective times each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendments thereto became or becomes effective and as of the date hereof, the Registration Statement, any Rule 462(b) Registration Statement and any amendments and supplements thereto complied and will comply in all material respects with the requirements of the Securities Act. The conditions for the use of Form S-3, as set forth in the General Instructions thereto, have been complied with and the Registration Statement meets, and the offering and sale of the Securities as contemplated hereby complies with, the requirements of Rule 415(a)(1)(x) under the Securities Act (including without limitation, Rule 415(a)(5)). The Registration Statement, as of the date hereof and each effective date with respect thereto, did not and will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. Neither the Prospectus nor any amendments or supplements thereto, as of their respective dates, and at each Applicable Time and Settlement Date (as defined below), as the case may be, included or will include an untrue statement of a material fact or omitted or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

The representations and warranties set forth in the immediately preceding paragraph shall not apply to statements in or omissions from the Registration Statement or the Prospectus, as amended or supplemented, made in reliance upon and in conformity with information furnished to the Company in writing by the Placement Agent expressly for use therein.

The copies of the Registration Statement and any Rule 462(b) Registration Statement and any amendments and supplements thereto, any other preliminary prospectus, each Issuer Free Writing Prospectus (as defined below) that is required to be filed with the Commission pursuant to Rule 433 under the Securities Act and the Prospectus and any amendments or supplements thereto delivered and to be delivered to the Placement Agent (electronically or otherwise) in connection with the offering of the Securities were and will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. "Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 under the Securities Act,

relating to the Securities that (i) is required to be filed with the Commission by the Company, (ii) is a “road show” that is a “written communication” within the meaning of Rule 433(d)(8)(i) under the Securities Act whether or not required to be filed with the Commission, or (iii) is exempt from filing pursuant to Rule 433(d)(5)(i) under the Securities Act because it contains a description of the Securities or of the offering that does not reflect the final terms, and all free writing prospectuses that are listed in Exhibit F hereto, in each case in the form furnished (electronically or otherwise) to the Placement Agent for use in connection with the offering of the Securities.

Each Issuer Free Writing Prospectus relating to the Securities, as of its issue date and as of each Applicable Time and Settlement Date, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified; each Issuer Free Writing Prospectus, as supplemented by and taken together with the Prospectus, as of its issue date, the Applicable Time and Settlement Date, will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances, prevailing at that time, not misleading. The foregoing sentence does not apply to statements in or omissions from any issuer free writing prospectus based upon and in conformity with written information furnished to the Company by the Placement Agent specifically for use therein.

Each document incorporated by reference in the Registration Statement or the Prospectus heretofore filed, when it was filed (or, if any amendment with respect to any such document was filed, when such amendment was filed), conformed in all material respects with the requirements of the Exchange Act, and any further documents so filed and incorporated after the date of this Agreement will, when they are filed, conform in all material respects with the requirements of the Exchange Act; no such document when it was filed (or, if an amendment with respect to any such document was filed, when such amendment was filed), contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading; and no such document, when it is filed, will contain an untrue statement of a material fact or will omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading.

(2) *Company Capitalization.* The Company has an authorized capitalization as set forth in the Prospectus; the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and nonassessable.

(3) *Disclosure Regarding Outstanding Securities.* Except as disclosed in the Prospectus, there are no outstanding (A) securities or obligations of the Company or the subsidiaries of the Company (if applicable) required to be set forth in Exhibit 21.1 to the Company’s Form 10-K for the fiscal year ended December 31, 2016 (each a “Subsidiary,” and together, the “Subsidiaries”) convertible into or exchangeable for any capital stock of or partnership interests, membership interests or other equity interests, as the case may be, in the Company or any such Subsidiary, (B) warrants, rights or options to subscribe for or purchase from the Company or any Subsidiary any such capital stock or any such convertible or exchangeable securities or obligations, or (C) obligations of the Company or any Subsidiary to issue any securities or obligations, any such convertible or exchangeable securities or obligations, or any such warrants, rights or options the existence of which, in each case (A), (B) and (C), is required to be disclosed in the Registration Statement and the Prospectus and are not so disclosed.

(4) *Good Standing.* Each of the Company and the Subsidiaries has been duly incorporated or organized and is validly existing as a corporation, general or limited partnership or limited liability company, as the case may be, except to the extent, in the case of the Subsidiaries, that the failure

to be so organized or in good standing would not, individually or in the aggregate, reasonably be expected to have any material adverse effect on, or change with respect to, the assets, business operation, earnings, prospects, properties or financial condition, present or prospective, of the Company and its Subsidiaries taken as a whole (a “Material Adverse Effect” or “Material Adverse Change”) and is in good standing under the laws of its respective jurisdiction of incorporation or organization except to the extent that the failure to be so qualified or in good standing would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(5) *Corporate Power.* Each of the Company and the Subsidiaries have the corporate, partnership or limited liability company power, as the case may be, and authority to own their respective properties and conduct their respective businesses, each as described in each of the Registration Statement and the Prospectus except to the extent that the failure to have such power or authority would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and, in the case of the Company, to execute and deliver this Agreement and to consummate the transactions described in this Agreement.

(6) *Foreign Qualifications.* The Company and the Subsidiaries are duly qualified or licensed and in good standing in each jurisdiction where such qualification or license is required except where the failure, individually or in the aggregate, to be so qualified or licensed would not reasonably be expected to have a Material Adverse Effect.

(7) *No Prohibition on Dividends Payable by the Subsidiaries.* Except as disclosed in the Prospectus, no Subsidiary is contractually prohibited or restricted, directly or indirectly, from paying dividends or from making any other distribution with respect to the outstanding membership interests or other securities of such Subsidiary or from repaying to the Company or another subsidiary of the Company any amounts which may from time to time become due under any loans or advances to such Subsidiary from the Company or another subsidiary of the Company, or from transferring such Subsidiary’s property or assets to the Company or another subsidiary of the Company except for any such prohibitions and restrictions that would not individually or in the aggregate reasonably be expected to have a Material Adverse Effect or to the extent that any such restriction would currently materially limit the Company’s ability to pay dividends or that would be reasonably likely to materially limit the future payment of dividends on Common Stock.

(8) *Absence of Defaults.* Except as disclosed in the Prospectus, neither the Company nor any Subsidiary is in breach of or in default under (nor has any event occurred which with notice, lapse of time, or both would constitute a breach of, or default under), its respective organizational documents, or in the performance or observance of any obligation, agreement, covenant or condition contained in any license, indenture, mortgage, deed of trust, loan or credit agreement or other agreement or instrument to which the Company or any Subsidiary is a party or by which any of them or their respective properties or assets is bound, except for such breaches or defaults which would not reasonably be expected to have a Material Adverse Effect.

(9) *Absence of Conflicts.* The execution, delivery and performance of this Agreement and consummation of the transactions contemplated herein will not (A) conflict with, or result in any breach of, or constitute a default under (nor constitute any event which with notice, lapse of time, or both would constitute a breach of, or default under): (1) any provision of the organizational documents of the Company or any Subsidiary, or (2) any provision of any license, indenture, mortgage, deed of trust, loan or credit agreement or other agreement or instrument to which the Company or any Subsidiary is a party or by which any of them or their respective assets or properties may be bound or affected, or under any federal, state, local or foreign law, regulation or rule or any decree, judgment or order applicable to the Company or any Subsidiary, except in the case of clause (2) for such breaches or defaults which could

not reasonably be expected to have a Material Adverse Effect; or (B) result in the creation or imposition of any lien, charge, claim or encumbrance upon any property or asset of the Company or any Subsidiary, except for such liens, charges, claims or encumbrances which would not reasonably be expected to have a Material Adverse Effect.

(10) *Authorization of Agreement.* This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally, and by general equitable principles, and except to the extent that the indemnification and contribution provisions of Section 10 hereof may be limited by federal or state securities laws and public policy considerations in respect thereof.

(11) *Absence of Further Requirements.* No approval, authorization, consent or order of or filing with any federal, state, local or foreign governmental or regulatory commission, board, body, authority or agency is required in connection with the Company's execution, delivery and performance of this Agreement, the consummation of the transactions contemplated herein by the Company, including the Company's issuance, sale and delivery of the Securities, other than (A) such as have been obtained, or will have been obtained at the Settlement Date (as defined below), as the case may be, under the Securities Act and the Exchange Act, (B) any necessary qualification under the securities or "blue sky" laws of the various jurisdictions in which the Securities are being offered by the Placement Agent, or (C) any such approvals, authorizations, consents, orders, or filings that if not obtained or made, would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect or which would not reasonably be expected to have a material adverse effect on the Company's ability to perform its agreed upon obligations under this Agreement.

(12) *Possession of Licenses and Permits.* Each of the Company and the Subsidiaries has all necessary licenses, authorizations, consents and approvals and has made all necessary filings required under any federal, state, local or foreign law, regulation or rule, and has obtained all necessary authorizations, consents and approvals from other persons, required in order to conduct their respective businesses as described in the Prospectus, except to the extent that any failure to obtain or have any such licenses, authorizations, consents or approvals or to make any such filings would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; neither the Company nor any of the Subsidiaries is in violation of, in default under, or has received any notice regarding a possible violation, default or revocation of any such license, authorization, consent or approval or any federal, state, local or foreign law, regulation or rule or any decree, order or judgment applicable to the Company or any of the Subsidiaries, the effect of which would reasonably be expected to result in a Material Adverse Change.

(13) *Permitted Free Writing Prospectuses.* Except for the Issuer Free Writing Prospectuses identified in Exhibit F hereto, the Company has not prepared, used or referred to, and will not, without the prior written consent of the Placement Agent, prepare, use or refer to, any Free Writing Prospectus.

(14) *Company Not an Ineligible Issuer.* (i) At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the Securities Act) of the Securities and (ii) as of the date hereof, the Company was not and is not an Ineligible Issuer (as defined in Rule 405 of the Securities Act Regulations), without taking account of any determination by the Commission pursuant to Rule 405 of the Securities Act that it is not necessary that the Company be considered an Ineligible Issuer.

(15) *Filing of Registration Statement.* The Company filed the Registration Statement with the Commission before using any Issuer Free Writing Prospectus.

(16) *Absence of Proceedings.* Except as disclosed in the Prospectus, there are no actions, suits, proceedings, inquiries or investigations pending or, to the knowledge of the Company, threatened against the Company or any Subsidiary or, to the extent that such proceeding affects the properties or assets of the Company or any Subsidiary, any of their respective officers and directors or to which the properties, assets or rights of any such entity are subject, at law or in equity, before or by any federal, state, local or foreign governmental or regulatory commission, board, body, authority, arbitral panel or agency which could result in a judgment, decree, award or order that would reasonably be expected to have a Material Adverse Effect.

(17) *Financial Statements.* The consolidated financial statements of the Company and its subsidiaries present fairly the consolidated financial position of the Company and its subsidiaries, as of the dates indicated and consolidated results of operations and changes in financial position and cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles as applied in the United States and on a consistent basis during the periods involved and in accordance with Regulation S-X promulgated by the Commission; the financial statement schedules included or incorporated by reference in the Prospectus have been compiled on a basis consistent with the financial statements; no pro forma financial information, financial statements or supporting schedules other than the historical financial statements are required to be included in the Registration Statement or the Prospectus.

(18) *Independent Accountants.* KPMG LLP, whose reports on the consolidated financial statements of the Company and its subsidiaries constitute part of the Prospectus, is, and was during the periods covered by its reports, independent as required by the Securities Act.

(19) *No Material Adverse Change.* Subsequent to the respective dates of the financial statements, and except as may be otherwise disclosed in the Prospectus, there has not been (A) any Material Adverse Change or any development or transaction that would reasonably be expected to result in a Material Adverse Change, whether or not arising in the ordinary course of business, (B) any transaction that is material to the Company and the Subsidiaries taken as a whole, contemplated or entered into by the Company or any of the Subsidiaries, (C) any obligation, contingent or otherwise, directly or indirectly incurred by the Company or any Subsidiary that is material to the Company and the Subsidiaries taken as a whole or (D) any dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock or any Subsidiary on any of its equity interests.

(20) *Description of Securities.* The Common Stock conforms in all material respects to the descriptions thereof contained in the Prospectus.

(21) *Absence of Registration Rights.* There are no persons with registration or other similar rights to have any equity or debt securities of the Company or the Subsidiaries, including securities which are convertible into or exchangeable or redeemable for equity securities of the Company or the Subsidiaries, registered pursuant to the Registration Statement or otherwise registered by the Company under the Securities Act.

(22) *Authorization of Securities.* The Securities have been duly authorized and, when issued and duly delivered against payment therefor as contemplated by this Agreement, will be validly issued, fully paid and non-assessable, free and clear of any pledge, lien, encumbrance, security interest or

other claim, and the issuance and sale of the Securities by the Company is not subject to preemptive or other similar rights arising by operation of law, under the organizational documents of the Company or any Subsidiary or under any agreement to which the Company or any Subsidiary is a party or otherwise.

(23) *NASDAQ.* The Common Stock has been registered under Section 12(b) of the Exchange Act and listed on the NASDAQ. The Company is in compliance with the rules of the NASDAQ, including, without limitation, the requirements for continued listing of the Common Stock on the NASDAQ, and there are no proceedings pending or, to the knowledge of the Company, threatened or contemplated, and the Company has not received any notice from the NASDAQ regarding the revocation of such listing or otherwise regarding the delisting of shares of the Common Stock from the NASDAQ. The Company has applied to have the Securities listed on the NASDAQ. The Company will provide the Placement Agent with written notice of the approval of the Securities for listing on the NASDAQ, and, upon such notice, the Securities will be approved for listing on the NASDAQ, subject to official notice of issuance;

(24) *Absence of Stabilization and Manipulation.* The Company has not taken, directly or indirectly, any action which is designed to or which has constituted or which might reasonably be expected to cause or result in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(25) *Absence of Registration Requirements.* Neither the Company nor any of its affiliates (A) is required to register as a “broker” or “dealer” in accordance with the provisions of the Exchange Act, or (B) directly, or indirectly through one or more intermediaries, controls or has any other association with (within the meaning of Article I of the By-laws of the Financial Industry Regulatory Authority (“FINRA”)) any member firm of FINRA.

(26) *Form of Certificates.* The form of certificate used to evidence the Common Stock complies in all material respects with all applicable statutory requirements, any applicable requirements of the organizational documents of the Company and the requirements of the NASDAQ.

(27) *Title to Property.* The Company and the Subsidiaries have good and marketable title in fee simple to all real property, if any, and good title to all personal property, if any, owned by them, in each case free and clear of all liens, security interests, pledges, charges, encumbrances, claims, restrictions, mortgages and defects in such title (collectively, the “Encumbrances”), except such Encumbrances that are disclosed in the Prospectus or would not reasonably be expected to have a Material Adverse Effect; any real or personal property leased by the Company or any Subsidiary is held under a lease which is a valid and binding agreement, enforceable against the Company or such Subsidiary (to the extent a party thereto) and, to the Company’s knowledge, the other parties thereto, except (A) as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors’ rights generally, and by general principles of equity, and except to the extent that the indemnification and contribution provisions of Section 10 hereof may be limited by federal or state securities laws and public policy considerations in respect thereof, (B) as otherwise disclosed in the Prospectus or (C) for such exceptions that would not reasonably be expected to have a Material Adverse Effect.

(28) *Mortgages.* Except as disclosed in the Prospectus, the mortgages, if any, encumbering any real property owned in fee simple by the Company or a Subsidiary are not and will not be: (A) convertible (in the absence of foreclosure) into an equity interest in such real property or in the Company or any Subsidiary, (B) cross-defaulted to any indebtedness other than indebtedness of the Company or any of the Subsidiaries or (C) cross-collateralized to any property or assets not owned by the Company or any of the Subsidiaries.

(29) *Description of Legal Proceedings.* The descriptions of legal or governmental proceedings, contracts, leases and other legal documents in the Prospectus constitute fair and accurate summaries of such proceedings or documents, and there are no legal or governmental proceedings, contracts, leases or other legal documents that are known to the Company of a character required to be described in the Prospectus or filed as exhibits to the Registration Statement which are not so described or filed; all agreements between the Company or any of the Subsidiaries and third parties expressly referenced in the Prospectus are legal, valid and binding obligations of the Company or the Subsidiaries, to the extent a party thereto, and, to the knowledge of the Company, of the other parties thereto, enforceable against the Company or Subsidiaries in accordance with their respective terms, and, to the knowledge of the Company, of the other parties thereto, except to the extent enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and neither the Company nor any Subsidiary is in breach or default under any such agreements, except to the extent that the indemnification and contribution may be limited by federal or state securities laws and public policy considerations in respect thereof.

(30) *Possession of Intellectual Property.* The Company and the Subsidiaries own or possess adequate licenses or other rights to use all material patents, trademarks, service marks, trade names, copyrights, software licenses, trade secrets, other intangible property rights and know-how (collectively, "Intangibles") necessary for the Company and the Subsidiaries taken together as a whole (the "Consolidated Company") to conduct the business of the Consolidated Company as described in the Prospectus, and neither the Company nor any Subsidiary has received notice of infringement of or conflict with (and the Company and the Subsidiaries know of no such infringement of or conflict with) asserted rights of others with respect to any Intangibles which could reasonably be expected to have a Material Adverse Effect.

(31) *Accounting Controls.* The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that, with respect to the Consolidated Company, (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit preparation of the consolidated financial statements of the Company in conformity with generally accepted accounting principles as applied in the United States and to maintain asset accountability; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(32) *Disclosure Controls.* (A) the Company has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act), which (1) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared, (2) have been evaluated for effectiveness as of the end of the Company's last fiscal year, and (3) are effective in all material respects to perform the functions for which they were established, and (B) based on the evaluation of the Company's disclosure controls and procedures described above, the Company is not aware of (1) any material weakness in the design or operation of internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information, or (2) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting. Since the most recent evaluation of the Company's disclosure controls and procedures described above, there have been no significant changes in internal control over financial reporting or in other factors that could significantly affect internal control over financial reporting.



(33) *ERISA.* The Company and the Subsidiaries are in compliance in all material respects with all presently applicable provisions of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder (“*ERISA*”); no “reportable event” (as defined in *ERISA*) has occurred with respect to any “pension plan” (as defined in *ERISA*) for which the Company or any of the Subsidiaries would have any material liability; neither the Company nor any of the Subsidiaries has incurred and none of them expect to incur any material liability under (A) Title IV of *ERISA* with respect to termination of, or withdrawal from, any “pension plan” or (B) Section 412 or 4971 of the Internal Revenue Code of 1986, as amended, including the regulations and published interpretations thereunder (“*Code*”); each “pension plan” for which the Company or any of the Subsidiaries would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified in all material respects and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(34) *Tax Returns.* The Company and each of the Subsidiaries has filed on a timely basis all material federal, state, local and foreign tax returns required to be filed through the date hereof or have properly requested extensions thereof, and all such tax returns are true, correct and complete in all material respects, and have paid all material taxes required to be paid, including any tax assessment, fine or penalty levied against the Company or any of the Subsidiaries; and no tax deficiency has been asserted against any such entity, nor does any such entity know of any tax deficiency which is likely to be asserted against any such entity which, individually or in the aggregate, if determined adversely to any such entity, could reasonably be expected to have a Material Adverse Effect; all material tax liabilities are adequately provided for on the respective books of such entities.

(35) *Legal, Tax or Accounting Advice.* The Company has not relied upon the Placement Agent or legal counsel for the Placement Agent for any legal, tax or accounting advice in connection with the offering and sale of the Securities.

(36) *Insurance.* The Company maintains insurance, including title insurance (in each case, issued by insurers of recognized financial responsibility) of the types and in the amounts generally deemed adequate for the business of the Company and its Subsidiary and generally consistent with insurance coverage maintained by similar companies in similar businesses, including, but not limited to, directors and officers liability insurance, title insurance, insurance covering real and personal property owned or leased by the Company and the Subsidiaries against theft, damage, destruction, environmental liabilities, acts of vandalism, terrorism, earthquakes, floods and all other risks customarily insured against, all of which insurance is in full force and effect.

(37) *Environmental Laws.* The Company and the Subsidiaries have received all permits, licenses or other approvals required of them under applicable federal, state, local and foreign occupational safety and health and environmental laws, regulations and rules to conduct the business of the Consolidated Company, and the Company and the Subsidiaries are in compliance with all terms and conditions of any such permits, licenses or approvals, except for any failure to have required permits, licenses or other approvals or to comply with the terms and conditions of such permits, licenses or approvals which would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(38) *Absence of Impermissible Transactions.* None of the Company, any of the Subsidiaries or, to the knowledge of the Company, any officer, director, employee or agent purporting to act on behalf of the Company or any of the Subsidiaries has at any time (A) made any contributions to any candidate for political office, or failed to disclose fully any such contributions, in violation of law, (B)

made any payment of funds or received or retained any funds in violation of any law, rule or regulation or of a character required to be disclosed in the Prospectus, or (C) engaged in any material transactions, maintained any bank account or used any material corporate funds except for transactions, bank accounts and funds which have been or are, as applicable, properly reflected in the books and records of the Company and the Subsidiaries.

(39) *Absence of Indebtedness.* Except as disclosed in the Prospectus, there are no material outstanding loans, advances or guarantees of indebtedness by the Company or any of the Subsidiaries to or for the benefit of any of the officers or directors of the Company or any officers and or directors of the Subsidiaries or any of the members of the immediate families of any such officers or directors.

(40) *Issued Securities.* All securities issued by the Company, any of the Subsidiaries or any trusts established by the Company or any of the Subsidiaries have been issued and sold in compliance with (A) all applicable federal and state securities laws and (B) the applicable corporate or partnership law of the jurisdiction of incorporation or organization of the Company or Subsidiary, as applicable.

(41) *Lessees.* Except as disclosed in the Prospectus, to the Company's knowledge, no lessee of any portion of any of the real properties leased or owned by the Company or any of the Subsidiaries (collectively, the "Properties") is in default under any of the leases governing such Properties and there is no event which, but for the passage of time or the giving of notice or both, would constitute a default under any of such leases, except such defaults that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect.

(42) *Hazardous Materials.* To the Company's knowledge neither the Company nor any of the Subsidiaries has any liability under any applicable environmental, health, safety or similar law or otherwise relating to any Hazardous Material (as hereinafter defined) and there are no notices of potential liability or claims pending or, to the knowledge of the Company, threatened against the Company or any of the Subsidiaries or concerning any of the Properties under any applicable environmental, health, safety or similar law or otherwise relating to any Hazardous Material, except for such liabilities or claims which would not reasonably be expected to have a Material Adverse Effect; neither the Company nor any of the Subsidiaries or, to the knowledge of the Company, any other person, has contaminated or caused conditions that threaten to contaminate any of the Properties with Hazardous Materials, except for such contamination or threats of contamination which could not reasonably be expected to have a Material Adverse Effect; neither the Properties nor any other land ever owned by the Company or any of the Subsidiaries is included on or, to the knowledge of the Company, is proposed for inclusion on the National Priorities List pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §. 9601 et seq., or any similar list or inventory of contaminated properties. As used herein, "Hazardous Material" shall mean any hazardous material, hazardous waste, hazardous substance, hazardous constituent, toxic substance, pollutant, contaminant, asbestos, petroleum, petroleum waste, radioactive material, biohazardous material, explosive or any other material, the presence of which in the environment is prohibited, regulated, or serves as the basis of liability, as defined, listed, or regulated by any applicable federal, state, or local environmental law, ordinance, rule, or regulation.

(43) *Compliance with Securities Laws.* In connection with the offer and sale of the Securities, the Company has not offered shares of its Common Stock or any other securities convertible into or exchangeable or exercisable or redeemable for Common Stock in a manner in violation of the Securities Act; and the Company has not distributed and will not distribute any offering material in

connection with the offer and sale of the Securities except for the Prospectus Supplement, the Prospectus and any Issuer Free Writing Prospectus or the Registration Statement.

(44) *Lending Relationship.* Except as disclosed in the Prospectus, neither the Company nor any of its subsidiaries has any outstanding borrowings from, or is a party to any line of credit, credit agreement or other credit facility or otherwise has a borrowing relationship with, any bank or other lending institution affiliated with the Placement Agent, and the Company does not intend to use any of the proceeds from the sale of the Securities to repay any debt owed to the Placement Agent or any affiliate thereof.

(45) *Absence of Finders' Fees.* The Company has not incurred any liability for any finder's fees or similar payments in connection with the transactions herein contemplated.

(46) *No Other Contracts.* Other than this Agreement, there are no contracts, agreements or understandings between the Company or any of its subsidiaries and any person that would give rise to a valid claim against the Company or any of its subsidiaries or the Placement Agent for a brokerage commission, finder's fee or other like payment with respect to the consummation of the transactions contemplated by this Agreement.

(47) *Proprietary Trading by the Placement Agent.* The Company acknowledges and agrees that the Placement Agent has informed the Company that the Placement Agent may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell shares of Common Stock for its own account while this Agreement is in effect, and shall be under no obligation to purchase Securities on a principal basis pursuant to this Agreement, except as otherwise agreed by the Placement Agent in the Placement Notice (as amended by the corresponding Acceptance, if applicable); provided, that no such purchase or sales shall take place while a Placement Notice is in effect (except (i) as agreed by the Placement Agent in the Placement Notice (as amended by the corresponding Acceptance, if applicable) or (ii) to the extent the Placement Agent may engage in sales of Placement Securities purchased or deemed purchased from the Company as a "riskless principal" or in a similar capacity).

(48) *FINRA Matters.* The Company meets the requirements for use of Form S-3 under the Securities Act specified in FINRA Conduct Rule 5110(B)(7)(C)(i).

(49) *Related Party Transactions.* Except as disclosed in the Prospectus, no relationship, direct or indirect, exists between or among the Company or any of the Subsidiaries on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company or any of the Subsidiaries on the other hand, that is required by the Securities Act to be described in the Prospectus and which is not so described.

(50) *Compliance with Sarbanes-Oxley.* The Company and the Subsidiaries and, to the knowledge of the Company, the officers and directors of the Company and the Subsidiaries, in their capacities as such, are, and at the Settlement Date (as defined below) and any Applicable Time will be, in compliance in all material respects with the provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder or implementing the provisions thereof (the "Sarbanes-Oxley Act").

(51) *Investment Company Act.* The Company is not and, after giving effect to the offering and sale of the Securities, will not be an "investment company", as such terms are defined in the Investment Company Act of 1940, as amended (the "Investment Company Act").

(52) *Statistical and Market Data.* The statistical and market related data included in the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate.

(b) Certificates. Any certificate signed by any officer of the Company delivered to the Placement Agent or to counsel for the Placement Agent pursuant to the terms or provisions of this Agreement shall be deemed a representation and warranty by the Company to the Placement Agent as to the matters covered thereby.

#### **SECTION 6. Sale and Delivery to the Placement Agent; Settlement.**

(a) Sale of Placement Securities. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, upon the Placement Agent's acceptance of the terms of a Placement Notice or upon receipt by the Placement Agent of an Acceptance, as the case may be, and unless the sale of the Placement Securities described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, the Placement Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Securities up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that the Placement Agent will be successful in selling Placement Securities, (ii) the Placement Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Securities for any reason other than a failure by the Placement Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Securities as required under this Section 6, and (iii) the Placement Agent shall be under no obligation to purchase Securities on a principal basis pursuant to this Agreement, except as otherwise agreed by the Placement Agent in the Placement Notice (as amended by the corresponding Acceptance, if applicable).

(b) Settlement of Placement Securities. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Securities will occur on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "Settlement Date"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Securities sold (the "Net Proceeds") will be equal to the aggregate sales price received by the Placement Agent at which such Placement Securities were sold, after deduction for (i) the Placement Agent's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to the Placement Agent hereunder pursuant to Section 8(a) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(c) Delivery of Placement Securities. On or before each Settlement Date, concurrently with the receipt by the Company of the Net Proceeds due to the Company in respect of such Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Securities being sold by crediting the Placement Agent's or its designee's account (provided the Placement Agent shall have given the Company written notice of such designee prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Placement Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Securities on a Settlement Date, the Company agrees that, in addition to and in no way limiting the rights and obligations set forth in Section 10(a)

hereto, it will (i) hold the Placement Agent harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to the Placement Agent any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(d) Denominations; Registration. If requested by the Placement Agent at least one Business Day prior to the Settlement Date, then in lieu of electronic transfer, certificates for the Securities shall be delivered to the Placement Agent or its designee in such denominations and registered in such names as the Placement Agent shall have specified in such request. The certificates for the Securities will be made available for examination and packaging by the Placement Agent in The City of New York not later than noon (New York time) on the Business Day prior to the Settlement Date.

**SECTION 7. Covenants of the Company.** The Company covenants with the Placement Agent as follows:

(a) Registration Statement Amendment. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Securities is required to be delivered by the Placement Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify the Placement Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any comment letter from the Commission or any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information; (ii) the Company will prepare and file with the Commission, promptly upon the Placement Agent's request, any amendments or supplements to the Registration Statement or Prospectus that, in the Placement Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Securities by the Placement Agent (provided, however, that the failure of the Placement Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Placement Agent's right to rely on the representations and warranties made by the Company in this Agreement); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Securities or a security convertible into the Placement Securities unless a copy thereof has been submitted to the Placement Agent within a reasonable period of time before the filing and the Placement Agent has not reasonably objected thereto (provided, however, that the failure of the Placement Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Placement Agent's right to rely on the representations and warranties made by the Company in this Agreement) and the Company will furnish to the Placement Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act (without reliance on Rule 424(b)(8) of the Securities Act).

(b) Notice of Commission Stop Orders. The Company will advise the Placement Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any other order preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus, or of the suspension of the qualification of the Placement Securities for offering or sale in any jurisdiction or of the loss or suspension of any exemption from any such qualification, or of the initiation or threatening of any proceedings for any of such purposes, or of any examination pursuant to Section 8(e) of the

Securities Act concerning the Registration Statement or if the Company becomes the subject of a proceeding under Section 8A of the Securities Act in connection with the offering of the Securities. The Company will make every reasonable effort to prevent the issuance of any stop order, the suspension of any qualification of the Securities for offering or sale and any loss or suspension of any exemption from any such qualification, and if any such stop order is issued or any such suspension or loss occurs, to obtain the lifting thereof at the earliest possible moment.

(c) Delivery of Registration Statement and Prospectus. Except to the extent such documents have been publicly filed with the Commission pursuant to EDGAR, the Company will furnish to the Placement Agent and its counsel (at the expense of the Company) copies of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus, and any Issuer Free Writing Prospectuses, that are filed with the Commission during any period in which a Prospectus relating to the Placement Securities is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities and at such locations as the Placement Agent may from time to time reasonably request.

(d) Continued Compliance with Securities Laws. If at any time when a Prospectus is required by the Securities Act to be delivered in connection with a pending sale of the Placement Securities (including, without limitation, pursuant to Rule 172 under the Securities Act), any event shall occur or condition shall exist as a result of which it is necessary to amend the Registration Statement together with the Prospectus in order that the Prospectus will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser, or if it shall be necessary at any such time to amend the Registration Statement together with the Prospectus in order to comply with the requirements of the Securities Act, the Company will promptly notify the Placement Agent to suspend the offering of Placement Securities during such period and the Company will promptly prepare and file with the Commission such amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement and the Prospectus comply with such requirements, and the Company will furnish to the Placement Agent such number of copies of such amendment or supplement as the Placement Agent may reasonably request. If at any time following the issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted, conflicts or would conflict with the information contained in the Registration Statement or the Prospectus or included, includes or would include an untrue statement of a material fact or together with the Prospectus omitted, omits or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances, prevailing at that subsequent time, not misleading, the Company will promptly notify the Placement Agent to suspend the offering of Placement Securities during such period and the Company will, subject to Section 7(a) hereof, promptly amend or supplement such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(e) Blue Sky and Other Qualifications. The Company will use its best efforts, in cooperation with the Placement Agent, to qualify the Placement Securities for offering and sale, or to obtain an exemption for the Securities to be offered and sold, under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Placement Agent may designate and to maintain such qualifications and exemptions in effect for so long as required for the distribution of the Securities (but in no event for less than one year from the date of this Agreement); provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject. In each

jurisdiction in which the Placement Securities have been so qualified or exempted, the Company will file such statements and reports as may be required by the laws of such jurisdiction to continue such qualification or exemption, as the case may be, in effect for so long as required for the distribution of the Placement Securities (but in no event for less than one year from the date of this Agreement).

(f) Rule 158. The Company will timely file such reports pursuant to the Exchange Act as are necessary in order to make generally available to its securityholders as soon as practicable an earnings statement for the purposes of, and to provide to the Placement Agent the benefits contemplated by, the last paragraph of Section 11(a) of the Securities Act.

(g) Use of Proceeds. The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Prospectus under "Use of Proceeds."

(h) Listing. During any period in which the Prospectus relating to the Placement Securities is required to be delivered by the Placement Agent under the Securities Act with respect to a pending sale of the Placement Securities (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Securities to be listed on the NASDAQ.

(i) Filings and Compliance with the NASDAQ. The Company will (i) timely file with the NASDAQ all material documents and notices required by the NASDAQ of companies that have securities traded on the NASDAQ, and (ii) comply, in all respects, with all rules and requirements of the NASDAQ as applicable to companies traded on the NASDAQ.

(j) Reporting Requirements. The Company, during any period when the Prospectus is required to be delivered under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act.

(k) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, the Company shall provide the Placement Agent notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Securities offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; provided, that such notice shall not be required in connection with the (i) issuance, grant or sale of restricted stock, Common Stock, LTIP units, options to purchase Common Stock, or Common Stock issuable upon the exercise of options or other equity awards pursuant to any stock option, stock bonus or other stock or compensatory plan or arrangement described in the Prospectus, (ii) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets described in the Prospectus, or (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company has in effect or may adopt from time to time, provided the implementation of such new plan is disclosed to the Placement Agent in advance.

(l) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Securities, advise the Placement Agent promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to the Placement Agent pursuant to this Agreement during such fiscal quarter.

(m) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by the Placement Agent or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior officers, during regular business hours and at the Company's principal offices, as the Placement Agent may reasonably request.

(n) Disclosure of Sales. The Company will, if applicable, disclose in its quarterly reports on Form 10-Q and in its annual report on Form 10-K the number of Placement Securities sold through the Placement Agent during the most recent fiscal quarter, the Net Proceeds to the Company and the compensation paid or payable by the Company to the Placement Agent with respect to such Placement Securities.

(o) Representation Dates; Certificate. On or prior to the date that the Securities are first sold pursuant to the terms of this Agreement and:

(i) each time the Company files the Prospectus relating to the Placement Securities or amends or supplements the Registration Statement or the Prospectus relating to the Placement Securities (other than amendments or supplements that are filed solely to report sales of the Placement Securities pursuant to this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Securities;

(ii) each time the Company files an annual report on Form 10-K under the Exchange Act;

(iii) each time the Company files its quarterly reports on Form 10-Q under the Exchange Act; and

(iv) each time the Company files a report on Form 8-K containing amended financial information (other than an earnings release, to "furnish" information pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassifications of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "Representation Date");

the Company shall furnish the Placement Agent with a certificate, in the form attached hereto as Exhibit E, within two (2) Trading Days of any Representation Date. The requirement to provide a certificate under this Section 7(o) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date; provided, however, that such waiver shall not apply for any Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Securities following a Representation Date when the Company relied on such waiver and did not provide the Placement Agent with a certificate under this Section 7(o), then before the Company delivers the Placement Notice or the Placement Agent sells any Placement Securities, the Company shall provide the Placement Agent with a certificate, in the form attached hereto as Exhibit E, dated the date of the Placement Notice.

(p) Legal Opinions. On or prior to the date that the Securities are first sold pursuant to the terms of this Agreement and within two (2) Trading Days after each Representation Date (excluding



Representation Dates with regard to the time the Company files its quarterly reports on Form 10-Q) with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit E for which no waiver is applicable, the Company shall cause to be furnished to the Placement Agent (i) a written opinion of Duane Morris LLP, corporate counsel to the Company (“Company Corporate Counsel”), or other counsel satisfactory to the Placement Agent, in form and substance reasonably satisfactory to the Placement Agent and its counsel, dated the date that the opinion is required to be delivered, substantially similar to the form attached hereto as Exhibit D, and (ii), unless waived by the Placement Agent, a written opinion of Goodwin Procter LLP, counsel to the Placement Agent (“Counsel to the Placement Agent”), or other counsel satisfactory to the Placement Agent, in form and substance reasonably satisfactory to the Placement Agent, dated the date that the opinion is required to be delivered; provided, however, that in lieu of such opinions for subsequent Representation Dates, counsel may furnish the Placement Agent with a letter (a “Reliance Letter”) to the effect that the Placement Agent may rely on a prior opinion delivered under this Section 7(p) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Representation Date).

(q) Comfort Letter. On or prior to the date that the Securities are first sold pursuant to the terms of this Agreement and within two (2) Trading Days after each Representation Date (excluding Representation Dates with regard to the time the Company files its quarterly reports on Form 10-Q) with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit E for which no waiver is applicable, the Company shall cause its independent accountants (and any other independent accountants whose report is included in the Prospectus) to furnish the Placement Agent letters (the “Comfort Letters”), dated the date the Comfort Letter is delivered, in form and substance satisfactory to the Placement Agent, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act, the Exchange Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters” to underwriters in connection with registered public offerings.

(r) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or (ii) sell, bid for, or purchase the Securities to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Securities to be issued and sold pursuant to this Agreement other than the Placement Agent; provided, however, that the Company may bid for and purchase its Common Stock in accordance with Rule 10b-18 under the Exchange Act.

(s) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an “investment company,” as such term is defined in the Investment Company Act, assuming no change in the Commission’s current interpretation as to entities that are not considered an investment company.

(t) Securities Act and Exchange Act. The Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Securities as contemplated by the provisions hereof and the Prospectus.

(u) No Offer to Sell. Other than a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance in writing by the Company and the Placement Agent in its capacity as principal or agent hereunder, the Company (including its agents and representatives, other than the

Placement Agent in its capacity as such) will not, directly or indirectly, make, use, prepare, authorize, approve or refer to any free writing prospectus relating to the Securities to be sold by the Placement Agent as principal or agent hereunder.

(v) Sarbanes-Oxley Act. The Company and its subsidiaries will use their best efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act of 2002.

(w) Regulation M. If the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Company or the Common Stock, it shall promptly notify the Placement Agent and sales of the Placement Securities under this Agreement shall be suspended until that or other exemptive provisions have been satisfied in the judgment of each party.

**SECTION 8. Payment of Expenses.** The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and of each amendment and supplement thereto, (ii) the word processing, printing and delivery to the Placement Agent of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Securities, (iii) the preparation, issuance and delivery of the certificates for the Placement Securities to the Placement Agent, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Securities to the Placement Agent, (iii) the fees and disbursements of the counsel, accountants and other advisors to the Company, (iv) the qualification or exemption of the Placement Securities under securities laws in accordance with the provisions of Section 7(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Placement Agent in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplements thereto, (v) the printing and delivery to the Placement Agent of copies of any Permitted Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any costs associated with electronic delivery of any of the foregoing by the Placement Agent to investors, (vi) the fees and expenses of the transfer agent and registrar for the Securities, (vii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Placement Agent in connection with, the review by FINRA of the terms of the sale of the Securities, (viii) the fees and expenses incurred in connection with the listing of the Placement Securities on the NASDAQ, and (ix) the fees and disbursements of counsel to the Placement Agent up to an amount equal to \$30,000.

**SECTION 9. Conditions of the Placement Agent's Obligations.** The obligations of the Placement Agent hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties of the Company contained in this Agreement or in certificates of any officer of the Company, including the form of certificate set forth in Exhibit E attached hereto, or any subsidiary of the Company delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:

(a) Opinions of Company Corporate Counsel and Counsel to the Placement Agent. On or prior to the date that Securities are first sold pursuant to the terms of this Agreement, the Company shall furnish to the Placement Agent the opinion, addressed to the Placement Agent, of Duane Morris LLP, corporate counsel for the Company, or other counsel satisfactory to the Placement Agent, in form and substance reasonably satisfactory to the Placement Agent and its counsel, dated the date that the opinion is required to be delivered, substantially similar to the form attached hereto as Exhibit D. Unless waived by the Placement Agent, Goodwin Procter LLP, counsel to the Placement Agent, or other counsel satisfactory to the Placement Agent, shall furnish to the Placement Agent, an opinion in form and

substance reasonably satisfactory to the Placement Agent dated the date that the opinion is required to be delivered.

(b) Effectiveness of Registration Statement. The Registration Statement and any Rule 462(b) Registration Statement shall be effective and shall be available for (i) all sales of Placement Securities issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Securities contemplated to be issued by any Placement Notice.

(c) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Securities for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus, or any Issuer Free Writing Prospectus, or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus, or any Issuer Free Writing Prospectus, or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus and any Issuer Free Writing Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(d) No Misstatement or Material Omission. The Placement Agent shall not have advised the Company that the Registration Statement or Prospectus, or any Issuer Free Writing Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Placement Agent's reasonable opinion is material, or omits to state a fact that in the Placement Agent's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(e) No Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business.

(f) Representation Certificate. The Placement Agent shall have received the certificate required to be delivered pursuant to Section 7(o) on or before the date on which delivery of such certificate is required pursuant to Section 7(o).

(g) Accountant's Comfort Letter. The Placement Agent shall have received the Comfort Letter required to be delivered pursuant Section 7(q) on or before the date on which such delivery of such opinion is required pursuant to Section 7(q).

(h) Approval for Listing. The Placement Securities shall have been approved for listing on the NASDAQ, subject only to notice of issuance.

(i) No Suspension. Trading in the Securities shall not have been suspended on the NASDAQ.

(j) Additional Documents. On each date on which the Company is required to deliver a certificate pursuant to Section 7(o), counsel for the Placement Agent shall have been furnished with such documents and opinions as they may require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, contained in this Agreement.

(k) Securities Act and Exchange Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424 under the Securities Act. The Company will have filed all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act.

(l) Termination of Agreement. If any condition specified in this Section 9 shall not have been fulfilled when and as required to be fulfilled, this Agreement may be terminated by the Placement Agent by notice to the Company, and such termination shall be without liability of any party to any other party except as provided in Sections 8 and 10 hereof and except that, in the case of any termination of this Agreement, Sections 5, 10, 11 and 19 hereof shall survive such termination and remain in full force and effect.

#### **SECTION 10. Indemnity and Contribution by the Company and the Placement Agent.**

(a) Indemnification by the Company. The Company agrees to indemnify, defend and hold harmless the Placement Agent and any person who controls the Placement Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any loss, expense, liability, damage or claim (including the reasonable cost of investigation) which, jointly or severally, the Placement Agent or any controlling person may incur under the Securities Act, the Exchange Act or otherwise, insofar as such loss, expense, liability, damage or claim arises out of or is based upon (1) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereof), any Issuer Free Writing Prospectus that the Company has filed or was required to file with the Commission or the Prospectus (the term Prospectus for the purpose of this Section 10 being deemed to include the Prospectus as of its date and as amended or supplemented by the Company), (2) any omission or alleged omission to state a material fact required to be stated in any such Registration Statement, or necessary to make the statements made therein not misleading, or (3) any omission or alleged omission from any such Issuer Free Writing Prospectus or Prospectus of a material fact necessary to make the statements made therein, in the light of the circumstances under which they were made, not misleading; except, in the case of each of clauses (1), (2) and (3), insofar as any such loss, expense, liability, damage or claim arises out of or is based upon any untrue statement or alleged untrue statement of a material fact or any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of the Prospectus and any Issuer Free Writing Prospectus, in the light of the circumstances under which they were made) not misleading, in each such case, to the extent contained in and in conformity with information furnished in writing by the Placement Agent to the Company expressly for use therein (that information being limited to that described in Section 10(b) hereof). The indemnity agreement set forth in this Section 10(a) shall be in addition to any liability which the Company may otherwise have. If any action is brought against the Placement Agent or any controlling person in respect of which indemnity may be sought against the Company pursuant to the foregoing paragraph of this Section 10(a), the Placement Agent shall promptly notify the Company in writing of the institution of such action, and the Company, as the case may be, shall if it so elects, assume the defense of such action, including the employment of counsel and payment of expenses; provided,

however, that any failure or delay to so notify the Company will not relieve the Company of any obligation hereunder, except to the extent that its ability to defend is materially prejudiced by such failure or delay. The Placement Agent or such controlling person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of the Placement Agent or such controlling person unless the employment of such counsel shall have been authorized in writing by the Company in connection with the defense of such action, or the Company shall not have employed counsel reasonably satisfactory to the Placement Agent or such controlling person, as the case maybe, to have charge of the defense of such action within a reasonable time or such indemnified party or parties shall have reasonably concluded (based on the advice of counsel) that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events such fees and expenses shall be borne by the Company and paid as incurred (it being understood, however, that the Company shall not be liable for the expenses of more than one separate firm of attorneys for the Placement Agent or such controlling persons in any one action or series of related actions in the same jurisdiction (other than local counsel in any such jurisdiction) representing the indemnified parties who are parties to such action). Anything in this paragraph to the contrary notwithstanding, the Company shall not be liable for any settlement of any such claim or action effected without its consent.

(b) Indemnification by the Placement Agent. The Placement Agent agrees to indemnify, defend and hold harmless the Company, the Company's directors, the Company's officers that signed the Registration Statement, any person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any loss, expense, liability, damage or claim (including the reasonable cost of investigation) which, jointly or severally, the Company or any such person may incur under the Securities Act, the Exchange Act or otherwise, insofar as such loss, expense, liability, damage or claim arises out of or is based upon (1) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereof), any Issuer Free Writing Prospectus that the Company has filed or was required to file with the Commission, or the Prospectus, (2) any omission or alleged omission to state a material fact required to be stated in any such Registration Statement, or necessary to make the statements made therein not misleading, or (3) any omission or alleged omission from any such Issuer Free Writing Prospectus or the Prospectus of a material fact necessary to make the statements made therein, in the light of the circumstances under which they were made, not misleading, but in each case only insofar as such untrue statement or alleged untrue statement or omission or alleged omission was made in such Registration Statement, Issuer Free Writing Prospectus or Prospectus in reliance upon and in conformity with information furnished in writing by the Placement Agent to the Company expressly for use therein. The statements set forth in the last sentence of the eighth paragraph under the caption "Plan of Distribution" in the Prospectus (to the extent such statements relate to the Placement Agent) constitute the only information furnished by or on behalf of the Placement Agent to the Company for the purposes of Section 5(a)(1) and this Section 10. The indemnity agreement set forth in this Section 10(b) shall be in addition to any liabilities that the Placement Agent may otherwise have.

If any action is brought against the Company or any such person in respect of which indemnity may be sought against the Placement Agent pursuant to the foregoing paragraph, the Company or such person shall promptly notify the Placement Agent in writing of the institution of such action and the Placement Agent shall, if it so elects, assume the defense of such action, including the employment of counsel and payment of expenses; provided, however, that any failure or delay to so notify the Placement Agent will not relieve the Placement Agent of any obligation hereunder, except to the extent that its ability to defend is materially prejudiced by such failure or delay. The Company or such person shall have the right to employ its own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of the Company or such person unless the employment of such counsel shall have been

authorized in writing by the Placement Agent in connection with the defense of such action or the Placement Agent shall not have employed counsel reasonably satisfactory to the Company or such person, as the case may be, to have charge of the defense of such action within a reasonable time or such indemnified party or parties shall have reasonably concluded (based on the advice of counsel) that there may be defenses available to it or them which are different from or additional to those available to the Placement Agent (in which case the Placement Agent shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events such fees and expenses shall be borne by the Placement Agent and paid as incurred (it being understood, however, that the Placement Agent shall not be liable for the expenses of more than one separate firm of attorneys in any one action or series of related actions in the same jurisdiction (other than local counsel in any such jurisdiction) representing the indemnified parties who are parties to such action). Anything in this paragraph to the contrary notwithstanding, the Placement Agent shall not be liable for any settlement of any such claim or action effected without its written consent.

(c) **Contribution.** If the indemnification provided for in this Section 10 is unavailable or insufficient to hold harmless an indemnified party under subsections (a) and (b) of this Section 10 in respect of any losses, expenses, liabilities, damages or claims referred to therein, then each applicable indemnifying party, in lieu of indemnifying such indemnified party, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, expenses, liabilities, damages or claims (i) in such proportion as is appropriate to reflect the relative benefits received by the Company and by the Placement Agent, each from the offering of the Securities, or (ii) if (but only if) the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company and the Placement Agent in connection with the statements or omissions which resulted in such losses, expenses, liabilities, damages or claims, as well as any other relevant equitable considerations. The relative benefits received by the Company shall be deemed to be equal to the gross proceeds from the offering of Securities (before deducting discounts and expenses) received by the Company and benefits received by the Placement Agent shall be deemed to be equal to the underwriting discounts and commissions received by the Placement Agent. The relative fault of the Company and of the Placement Agent shall be determined by reference to, among other things, whether the untrue statement or alleged untrue statement of a material fact or omission or alleged omission relates to information supplied by the Company or by the Placement Agent and the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The amount paid or payable by a party as a result of the losses, claims, damages and liabilities referred to above shall be deemed to include any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any claim or action.

The Company and the Placement Agent agree that it would not be just and equitable if contribution pursuant to this Section 10 were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in clause (i) and, if applicable, clause (ii) of subsection (c) above. Notwithstanding the provisions of this Section 10, the Placement Agent shall not be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by the Placement Agent and the liability of the Company pursuant to this Section 10 shall not exceed the gross proceeds received by the Company in the offering. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

**SECTION 11. Representations, Warranties and Agreements to Survive Delivery.** All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and

effect, regardless of any investigation made by or on behalf of the Placement Agent or controlling person, or by or on behalf of the Company, and shall survive delivery of the Securities to the Placement Agent.

## **SECTION 12. Termination of Agreement.**

(a) Termination; General. In addition to the right of the Placement Agent to terminate this Agreement pursuant to Section 9(l), the Placement Agent may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (i) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Placement Agent, impracticable or inadvisable to market the Securities or to enforce contracts for the sale of the Securities, or (iii) if trading in the Securities has been suspended or limited by the Commission or the NASDAQ, or if trading generally on the NYSE American, the NYSE or the NASDAQ has been suspended or limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, the FINRA or any other governmental authority, or a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or in Europe, or (iv) if a banking moratorium has been declared by either Federal or New York authorities.

(b) Termination by the Company. Notwithstanding any other provision of this Agreement, the Company shall have the right, by giving one (1) day's notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Upon termination of this Agreement pursuant to this Section 12(b), any outstanding Placement Notices shall also be terminated.

(c) Termination by the Placement Agent. Notwithstanding any other provision of this Agreement, the Placement Agent shall have the right, by giving one (1) day's notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time after the date of this Agreement.

(d) Automatic Termination. Unless earlier terminated pursuant to this Section 12, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Securities through the Placement Agent on the terms and subject to the conditions set forth in this Agreement, including all Exhibits hereto, and in the Placement Notices (as amended by any corresponding Acceptance, if applicable).

(e) Continued Force and Effect. This Agreement shall remain in full force and effect until its termination pursuant to Sections 12(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties.

(f) Effectiveness of Termination. Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided, however, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Placement Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Securities, such Placement Securities shall settle in accordance with the provisions of this Agreement.

(g) **Liabilities.** If this Agreement is terminated pursuant to this Section 12, such termination shall be without liability of any party to any other party except as provided in Sections 2 and 8 hereof, and except that, in the case of any termination of this Agreement, Section 5, Section 10, Section 11 and Section 19 hereof shall survive such termination and remain in full force and effect.

**SECTION 13. Notices.** Except as otherwise provided in this Agreement, all notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Placement Agent shall be directed to the Placement Agent at JMP Securities LLC, 600 Montgomery Street, Suite 1100, San Francisco, California 94111, Facsimile: (415) 835-8920, Attention: Equity Securities and notices to the Company shall be directed to it at the offices of the Company at 170 N. Radnor-Chester Road, Suite 250, Radnor, Pennsylvania 19087, fax no. (484) 801-4669, Attention of Chief Financial Officer.

**SECTION 14. Parties.** This Agreement shall inure to the benefit of and be binding upon the Placement Agent, the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Placement Agent, the Company and their respective successors and the controlling persons and officers and directors referred to in Section 10 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Placement Agent, the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from the Placement Agent shall be deemed to be a successor by reason merely of such purchase.

**SECTION 15. Adjustments for Stock Splits.** The parties acknowledge and agree that all stock-related numbers contained in this Agreement shall be adjusted to take into account any stock split, stock dividend or similar event effected with respect to the Securities.

**SECTION 16. Governing Law and Time.** THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

**SECTION 17. Effect of Headings.** The Section and Exhibit headings herein are for convenience only and shall not affect the construction hereof.

**SECTION 18. Permitted Free Writing Prospectuses.** The Company represents, warrants and agrees that, unless it obtains the prior consent of the Placement Agent, and the Placement Agent represents, warrants and agrees that, unless it obtains the prior consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405 under the Securities Act, required to be filed with the Commission. Any such free writing prospectus consented to by the Placement Agent or by the Company, as the case may be, is hereinafter referred to as a “Permitted Free Writing Prospectus.” The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus,” as defined in Rule 433 under the Securities Act, and has complied and will comply with the requirements of Rule 433 under the Securities Act applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit F hereto are Permitted Free Writing Prospectuses.



**SECTION 19. Absence of Fiduciary Relationship.** The Company acknowledges and agrees that:

(a) the Placement Agent is acting solely as agent and/or principal in connection with the public offering of the Securities and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and the Placement Agent, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not the Placement Agent has advised or is advising the Company on other matters, and the Placement Agent has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

(b) the public offering price of the Securities was not established by the Placement Agent; it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Placement Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) it is aware that the Placement Agent and its respective affiliates are engaged in a broad range of transactions which may involve interests that differ from or may conflict with those of the Company and the Placement Agent has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) it waives, to the fullest extent permitted by law, any claims it may have against the Placement Agent for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that the Placement Agent shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, or the employees or creditors of Company.

[Signature Page Follows]

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement by and among the Placement Agent and the Company in accordance with its terms.

Very truly yours,

MARINUS PHARMACEUTICALS, INC.

By: /s/ Edward F. Smith  
Name: Edward F. Smith  
Title: CFO

CONFIRMED AND ACCEPTED,  
as of the date first above written:

JMP SECURITIES LLC

By: /s/ David J. Kellman  
Name: David J. Kellman  
Title: Managing Director

EXHIBIT A

FORM OF PLACEMENT NOTICE

From: Marinus Pharmaceuticals, Inc.

Cc: [\_\_\_\_\_]

To: JMP Securities LLC

Subject: Equity Distribution—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Equity Distribution Agreement between Marinus Pharmaceuticals, Inc. (the “Company”) and JMP Securities LLC (the “Placement Agent”) dated October 31, 2017 (the “Agreement”), I hereby request on behalf of the Company that the Placement Agent sell up to [ ] shares of the Company’s common stock, par value \$0.001 per share, at a minimum market price of \$[ ] per share.

[ADDITIONAL SALES PARAMETERS MAY BE ADDED, SUCH AS THE MAXIMUM AGGREGATE OFFERING PRICE, THE TIME PERIOD IN WHICH SALES ARE REQUESTED TO BE MADE, SPECIFIC DATES THE SHARES MAY NOT BE SOLD ON, THE MANNER IN WHICH SALES ARE TO BE MADE BY THE PLACEMENT AGENT, AND/OR THE CAPACITY IN WHICH THE PLACEMENT AGENT MAY ACT IN SELLING SHARES (AS PRINCIPAL, AGENT, OR BOTH)]

EXHIBIT B

AUTHORIZED INDIVIDUALS FOR PLACEMENT NOTICES AND ACCEPTANCES

**JMP Securities LLC**

David Kellman, Managing Director

Gil Mogavero, Chief Compliance Officer

Kenneth Clausman, Managing Director

Andrew Mertz, Managing Director

**Marinus Pharmaceuticals, Inc.**

Christopher M. Cashman, President and Chief Executive Officer

Edward F. Smith, Chief Financial Officer

EXHIBIT C  
COMPENSATION

The Placement Agent shall be paid compensation equal to up to 3.0% of the gross proceeds from the sales of Securities pursuant to the terms of this Agreement.

EXHIBIT D

FORM OF OPINION OF COMPANY CORPORATE COUNSEL

(1) The Company's Registration Statement has become effective under the Securities Act; the Prospectus has been filed pursuant to Rule 424(b) under the Securities Act in the manner and within the time period required by Rule 424(b) under the Securities Act (without reference to Rule 424(b)(8) under the Securities Act); and, to our knowledge, no stop order suspending the effectiveness of the Registration Statement has been issued and no proceedings for that purpose have been instituted or are pending under the Act.

(2) All regulatory consents, authorizations, approvals and filings required to be obtained or made by the Company under the Applicable Laws (as hereinafter defined) for the issuance, sale and delivery of the Securities by the Company to you have been obtained or made; provided, however, that such counsel need not express any opinion with respect to any state securities laws or the rules of the NASDAQ Stock Market that may be applicable to the issuance, sale or delivery of the Securities.

(3) The execution and delivery by the Company of the Equity Distribution Agreement, the issuance of the Securities and the sale of the Securities by the Company to you pursuant to the Equity Distribution Agreement do not, and the performance by the Company of its obligations under the Equity Distribution Agreement will not, (A) violate any Applicable Laws, or (B) result in a default under or breach of any agreement filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 under Item 601(b)(10) of Regulation S-K under the Act; provided, however, that, for the purposes of this paragraph (3), such counsel need not express any opinion with respect to Federal or state securities laws, other antifraud laws and fraudulent transfer laws and the Employee Retirement Income Security Act of 1974 and related laws and the rules of the NASDAQ Stock Market; provided, further, that insofar as performance by the Company of its obligations under the Equity Distribution Agreement is concerned, such counsel need not express any opinion as to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles.

Such counsel may state that its opinion is limited to (i) the General Corporation Law of the State of Delaware; and (ii) those federal laws, rules and regulations of the United States of America and those laws, rules and regulations of the State of Delaware, in each case which, in its experience, without having made any special investigation as to the applicability of any specific laws, rules or regulations, are normally applicable to transactions of the type contemplated by the Equity Distribution Agreement (collectively, the "Applicable Laws"). No opinion need be expressed as to the effect on the matters covered by the opinion of the laws, rules or regulations of (i) the United States of America or the State of Delaware other than the Applicable Laws, (ii) any jurisdiction other than the United States of America and the State of Delaware or (iii) state securities laws, whether in any such case applicable directly or through the Applicable Laws.

Such counsel may state that it does not represent the Company as to intellectual property matters or FDA matters (and similar U.S. and foreign agencies).

Such counsel may also state that it has relied as to certain matters upon information obtained from public officials, officers of the Company and their respective subsidiaries and other sources believed by such counsel to be responsible, and that it has assumed that the certificates for the Securities conform to the specimen thereof examined by such counsel and have been duly countersigned and registered by the transfer agent and registrar of the Securities, that the Equity Distribution Agreement has been duly

authorized, executed and delivered by the Placement Agent, and that the signatures on all documents examined by such counsel are genuine, assumptions which it has not independently verified.

Such counsel shall also provide to the Placement Agent a letter, dated the date of the Prospectus Supplement, to the effect that as counsel to the Company, it reviewed the Registration Statement, the Prospectus, and the Prospectus Supplement and participated in discussions with representatives of the Placement Agent and those of the Company. Such counsel shall state that on the basis of such information (i) the Registration Statement and the Prospectus (in each case other than the financial statements and related notes thereto, the financial statement schedules and the other financial, statistical and accounting data included or incorporated by reference in, or which should be included or incorporated by reference in, the Registration Statement or the Prospectus, as to which we express no opinion), comply as to form in all material respects with the applicable requirements of the Securities Act and the rules and regulations promulgated thereunder and (ii) such counsel confirms to you that, no facts have come to such counsel's attention that cause such counsel to believe that (a) the Registration Statement, as of its most recent effective date, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements contained therein not misleading, or (b) the Prospectus, as of its date, contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading (in each case other than the financial statements and the related notes thereto, the financial statement schedules and the other financial, statistical, quantitative and accounting data included therein or which should be included therein, as to which such counsel expresses no view).

In addition, such counsel shall state that it does not know of any litigation or any governmental proceeding instituted or threatened against the Company or any of its consolidated subsidiaries that would be required to be disclosed in the Prospectus, as supplemented by the Prospectus Supplement, and is not so disclosed.

Such counsel shall be entitled to state that the limitations inherent in the independent verification of factual matters and the character of determinations involved in the registration process are such, however, that it does not assume any responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement, the Prospectus or the Prospectus Supplement. Such counsel may also state that it does not express any opinion or belief as to the financial statements or schedules or other financial data derived from accounting records or as to any statistical data contained in the Registration Statement, the Prospectus or the Prospectus Supplement, or as to the report of management's assessment of the effectiveness of internal control over financial reporting or the auditors' attestation report thereon, each as included in the Registration Statement, the Prospectus or the Prospectus Supplement.

EXHIBIT E

OFFICER CERTIFICATE

The undersigned Edward F. Smith is the Chief Financial Officer of Marinus Pharmaceuticals, Inc., a Delaware corporation (the "Company"). The undersigned hereby executes this Certificate in connection with the closing held as of the date hereof pursuant to the terms of that certain Equity Distribution Agreement, dated October 31, 2017 (the "Equity Distribution Agreement"), among the Company and JMP Securities LLC. Capitalized terms used herein without definition shall have the meanings given to such terms in the Equity Distribution Agreement.

The undersigned hereby further certifies, in his capacity as an officer of the Company, that:

1. The representations and warranties of the Company in the Equity Distribution Agreement are true and correct, as if made on and as of the date hereof, and the Company has complied with all of its obligations thereunder and satisfied all of the conditions on its part to be performed or satisfied at or prior to the date hereof;
2. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued and no proceedings for that purpose have been instituted or are pending or threatened under the Securities Act of 1933, as amended;
3. Subsequent to the respective dates as of which information is given in the Registration Statement or the Prospectus, there has not been (A) any Material Adverse Change, (B) any transaction, except as incurred in the ordinary course of business, that is material to the Company and its subsidiaries taken as a whole, (C) any obligation, direct or contingent, except as incurred in the ordinary course of business, that is material to the Company and its subsidiaries, taken as a whole, incurred by the Company or the Subsidiaries, (D) any change in the capital stock or outstanding indebtedness of the Company or any Subsidiary that is material to the Company and its subsidiaries, taken as a whole, or (E) any loss or damage (whether or not insured) to the Properties which has been sustained or will have been sustained which could reasonably be expected to have a Material Adverse Effect; and
4. Each of Duane Morris LLP and Goodwin Procter LLP, is entitled to rely on this Officers' Certificate in connection with the opinion that each firm is rendering pursuant to the Equity Distribution Agreement.

[Signature Page Follows]



IN WITNESS WHEREOF, the undersigned has signed their names on this [ ] day of [ ],  
20[ ].

MARINUS PHARMACEUTICALS, INC.

By: \_\_\_\_\_  
Name: Edward F. Smith  
Title: Chief Financial Officer

EXHIBIT F  
ISSUER FREE WRITING PROSPECTUSES

None.

**Certification of Chief Executive Officer Pursuant to  
Exchange Act Rules 13a-14(a) or 15d-14(a)**

I, Christopher M. Cashman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Marinus Pharmaceuticals, Inc.;
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(s) 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 15(d)-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(s) 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: October 31, 2017

/s/ Christopher M. Cashman  
Christopher M. Cashman,  
President and Chief Executive Officer

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**Certification of Chief Financial Officer Pursuant to  
Exchange Act Rules 13a-14(a) or 15d-14(a)**

I, Edward F. Smith, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Marinus Pharmaceuticals, Inc.;
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(s) 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 15(d)-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(s) 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: October 31, 2017

/s/ Edward F. Smith  
Edward F. Smith,  
Chief Financial Officer and Treasurer

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**Certification Pursuant to 18 U.S.C. Section 1350**

In connection with the quarterly report of Marinus Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, in the capacities and on the date indicated below, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 31, 2017

/s/ Christopher M. Cashman  
President and Chief Executive Officer  
(Principal executive officer)

Date: October 31, 2017

/s/ Edward F. Smith  
Chief Financial Officer and Treasurer  
(Principal financial and accounting officer)

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