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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 2, 2018

GEMPHIRE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37809**	**47-2389984**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

17199 N. Laurel Park Drive, Suite 401
Livonia, Michigan 48152
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (734) 245-1700

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☒

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to the Company's expectations regarding the timing of royalty payments under the License Agreement. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the success and timing of the Company's regulatory submissions and pre-clinical and clinical trials; regulatory requirements or developments; changes to the Company's clinical trial designs and regulatory pathways; changes in the Company's capital resource requirements; the Company's ability to obtain additional financing; the Company's ability to successfully market and distribute its product candidate, if approved; the Company's ability to obtain and maintain its intellectual property protection; and other factors discussed in the "Risk Factors" section of the Company's filings with the Securities and Exchange Commission from time to time. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Item 1.01 Entry into a Material Definitive Agreement.

Gemphire Therapeutics Inc. (the "Company") entered into an Amended and Restated License Agreement (the "License Agreement") with Pfizer Inc. ("Pfizer") on August 2, 2018, which amended and restated in full the Company's prior license agreement with Pfizer dated April 16, 2011 (the "Original Agreement").

Pursuant to the License Agreement, Pfizer has granted the Company a worldwide exclusive license to certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Pfizer retains the right to make, use and import gemcabene solely for internal research purposes.

Under the Original Agreement, in partial consideration for the rights granted by Pfizer, the Company agreed to issue shares of its common stock to Pfizer representing 15% of its fully diluted capital at the close of the Company's first arms-length Series A financing, which occurred on March 31, 2015. Accordingly, Pfizer became the holder of 675,250 shares of the Company's common stock.

Pursuant to the License Agreement, the Company agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first new drug application (or its foreign equivalent) in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene. Future milestone payments under the License Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

We have also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales as specified in the License Agreement until the later of: (i) five years after the first commercial sale in such country; (ii) the expiration of all regulatory or data exclusivity for gemcabene in such country; and (iii) the expiration or abandonment of the last valid claim of the licensed patents, including any patent term extensions or supplemental protection certificates in such country (collectively, the "Royalty Term"). The royalty rates range from the high single digits to the mid-teens depending on the level of net sales. The royalty rates are subject to reduction during certain periods when therapeutically-equivalent generic products represent a certain market share of prescription volume in the country. Under the License Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

The License Agreement will expire upon expiration of the last Royalty Term. On expiration (but not earlier termination), the Company will have a perpetual, exclusive, fully paid-up, royalty-free license under the licensed patent rights and related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Either party may terminate the License Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the License Agreement in the event that (i) the Company or any of its affiliates or sublicensees

contests or challenges, or supports or assists any third party to contest or challenge, Pfizer's ownership of or rights in, or the validity, enforceability or scope of, any of the patents licensed under the License Agreement or (ii) the Company or any of its affiliates or sublicensees fails to achieve the first commercial sale in at least one country by April 16, 2024. Furthermore, upon termination of the License Agreement by Pfizer for any of the foregoing reasons, the Company grants Pfizer, pursuant to the License Agreement, a non-exclusive, fully paid-up, royalty free, worldwide, transferrable, perpetual and irrevocable license to use any intellectual property rights arising from the development or commercialization of gemcabene by the Company and any trademarks identifying gemcabene and agrees to transfer regulatory filings and approvals to Pfizer or permit Pfizer to cross-reference and rely on such regulatory filings and approvals for gemcabene. The Company may terminate the License Agreement for convenience upon 90 days' written notice and payment of an early termination fee.

The foregoing descriptions of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference. The representations and warranties contained in the License Agreement were made only for the purposes of the agreement as of specific dates and may have been qualified by certain disclosures between the parties, among other limitations. The representations and warranties were made for the purposes of allocating contractual risk between the parties to the License Agreement and should not be relied upon as a disclosure of factual information relating to the Company or Pfizer.

Item 7.01. Regulation FD Disclosure.

On August 6, 2018, the Company issued a press release announcing the License Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. Information contained in or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of such website addresses in this Current Report on Form 8-K by incorporation by reference of the press release is as inactive textual references only.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and will not be incorporated by reference into any filing under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of any such website address in this Current Report on Form 8-K by incorporation by reference of the press release is as an inactive textual reference only.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT INDEX

Exhibit		Description
10.1	#	Amended and Restated License Agreement effective August 2, 2018 by and between Gemphire Therapeutics Inc. and Pfizer Inc.
99.1		Press Release dated August 6, 2018.

Portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been separately filed with the Securities and Exchange Commission.

SIGNATURE

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 hereunto duly authorized.

GEMPHIRE THERAPEUTICS INC.

Dated: August 6, 2018

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer

AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED LICENSE AGREEMENT (this "**Agreement**") is made effective as of the 2nd day of August, 2018 (the "**Effective Date**"), by and between Gemphire Therapeutics Inc., a Delaware corporation with offices at 17199 N. Laurel Park Dr., Suite 401, Livonia, MI 48152 ("**LICENSEE**"), and Pfizer Inc., a corporation organized and existing under the laws of Delaware with offices at 235 East 42nd Street, New York, NY 10017 ("**PFIZER**"). LICENSEE and PFIZER may, from time-to-time, be individually referred to as a "**Party**" and collectively referred to as the "**Parties**."

RECITALS

WHEREAS, PFIZER owns certain patents hereinafter referred and defined as Licensed Patents;

WHEREAS, PFIZER and Michigan Life Therapeutics, LLC previously entered into that certain License Agreement dated April 16, 2011 pursuant to which PFIZER granted Michigan Life Therapeutics, LLC a license to the Licensed Patents (the "**Original Agreement**");

WHEREAS, Michigan Life Therapeutics, LLC was merged with and into LICENSEE in October 2014, with LICENSEE as the surviving entity and successor to the Original Agreement; and

WHEREAS, PFIZER and LICENSEE wish to amend and restate the Original Agreement in its entirety on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS

1.1 "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "**control**" shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

1.2 "**Applicable Laws**" means all applicable laws, statutes, rules, regulations and guidelines, including, without limitation, all good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority.

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* Information redacted pursuant to a confidential treatment request by Gemphire Therapeutics Inc. under 5 U.S.C. §552(b)(4), Rule 406 under the Securities Act of 1933 and Rule 24b-2 of the Securities Exchange Act of 1934 and submitted separately with the Securities and Exchange Commission.

1.3 "**Business Day**" means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York are authorized or required by law to remain closed.

1.4 "**Calendar Quarter**" means the three (3) month period commencing as of the first day of the calendar quarter following the Effective Date, and each successive three (3) month period thereafter.

1.5 "**Calendar Year**" means the twelve (12) month period commencing as of January 1, 2018, and each successive twelve (12) month period thereafter.

1.6 "**Commercialize**" or "**Commercialization**" means to manufacture for sale, market, promote, distribute, and sell.

1.7 **"Commercially Reasonable Efforts"** means: (a) with respect to the further Development of the Product, the efforts and expenditures required to obtain Regulatory Approvals and/or for securing patents that is comparable to any of LICENSEE's products that are at a similar stage of development, and (b) with respect to Commercialization of the Product, efforts and expenditures that are comparable to those used for any of LICENSEE's products that are of similar commercial potential; provided, however, that in the event LICENSEE does not have another product that is in a similar stage of development or of similar commercial potential, "Commercially Reasonable Efforts" shall mean those efforts and expenditures that are comparable to those used by companies capitalized similarly to LICENSEE and for products that are in a similar stage of development or of similar commercial potential.

1.8 "**Common Stock**" means shares of the common stock of the LICENSEE, par value $.001 per share.

1.9 "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights to the other Party without breaching the terms of any agreement with a Third Party.

1.10 "**Data**" means any and all non-aggregated and aggregated research, pharmacology, pre-clinical, clinical, commercial, marketing, process development, manufacturing and other data or information, including investigator brochures and reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety data, in each case generated from, or related to, clinical studies or non-clinical studies, research or testing .

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1.11 "**Develop**" or "**Development**" means to conduct research and development activities necessary to obtain Regulatory Approval.

1.12 "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.13 "**First Commercial Sale**" means the first sale of the Product by LICENSEE, LICENSEE's Affiliates, or a sublicensee to a Third Party in a country in the Territory following receipt of Regulatory Approval for the Product in such country.

1.14 "**GAAP**" means generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

1.15 **"Generic Erosion"** means that a Generic Product alone has, or multiple Generic Products in the aggregate have, attained, on a Product-by-Product basis and on a country-by-country basis, at least [*] market share of prescription volume in a LICENSEE calendar quarter of the applicable Product in the applicable country, as measured by the IMS data or other marketing data issued by a reputable data source acceptable to both Parties.

1.16 **"Generic Product"** means, with respect to a particular country in the Territory, any pharmaceutical product that (a) is marketed for sale by a Third Party not authorized by Licensee, (b) receives Regulatory Approval (with or without pricing or reimbursement approval) in such country in full or partial reliance on the Regulatory Approval (but not necessarily pricing or reimbursement approval) of a Product, and (c) is determined by a Regulatory Authority to be therapeutically equivalent to and substitutable with a Product, it being acknowledged that the foregoing standard is intended to be consistent with the standard set forth in the introduction to the "Orange Book," as amended from time to time, or any analogous or comparable standard in any country outside of the United States. For avoidance of doubt, in the United States, a "Generic Product" as defined herein includes one approved under Section 505(j) of the Federal Food Drug and Cosmetic Act, as supplemented or amended.

1.17 "**IND**" means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of the Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in the relevant regulatory jurisdictions in the Territory, as applicable.

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1.18 "**Intellectual Property Rights**" means all trade secrets, copyrights, patents and other patent rights, trademarks, moral rights, Data and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.19 "**Licensed Data**" means all Data specifically related or directed to the Product that was (i) Controlled by PFIZER as of the date of the Original Agreement, and (ii) that was provided by PFIZER to LICENSEE in connection with the Original Agreement.

1.20 "**Licensed Patents**" means (a) the patents and patent applications listed in Schedule A, (b) all divisionals, continuations, and continuations-in-part that claim priority to the patents or patent applications described in subsection (a) that claim the Product, (c) all patents that have issued or in the future issue from any of the foregoing patent applications in subsections (a) and (b) that claim the Product, including utility, model and design patents and certificates of invention, (d) any reissues, renewals, extensions or additions of any of the foregoing, and (e) any foreign counterparts of any of the foregoing.

1.21 "**Licensed Technology**" means, collectively, the Licensed Patents and Licensed Data.

1.22 "**NDA/BLA**" means: (a) a new drug application or a new biologic license application filed with the FDA for authorization for marketing the Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.23 "**Net Sales**" means the gross amount of Products invoiced by LICENSEE, its sublicensees or any Affiliate, less (1) sales returns, and allowances actually paid, granted or accrued, including trade, quantity and cash discounts, chargebacks, rebates, and customary trade discounts actually taken, and (2) to the extent recorded in the gross amount invoiced, outbound freight, value added tax, sales or use taxes, and custom or excise duties. Net Sales shall be determined from the books and records of the LICENSEE and/or an Affiliate of the LICENSEE, as the case may be, and as maintained in accordance with GAAP consistently applied.

The following principles shall apply in the calculation of Net Sales:

1.23.1 In the case of any sale of Product which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Product is paid for, if paid for before shipment or invoice.

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1.23.2 In the case of any sale or other disposal of Product for non-cash consideration, Net Sales shall be calculated as the fair market price of the Product in the country of sale or disposal.

1.23.3 [*] of Net Sales of any Combination Products shall be included in determining Net Sales of the Product. For purposes of this Section 1.23.3, "**Combination Products**" means any pharmaceutical product containing: (a) the Product and (b) one or more other therapeutically active ingredient(s).

1.23.4 Unless otherwise specified herein, Net Sales shall be calculated in accordance with (and include the deductions as permitted by) GAAP generally and consistently applied.

1.24 "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.25 "**Product**" means Gemcabene or any salt, hydrate, solvate, anhydrous form, or polymorph thereof, including the monocalcium salt Gemcabene calcium, which is also identified as CI-1027, PF-01430506, and/or PD-072953.

1.26 "**Regulatory Approval**" means, with respect to the Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Regulatory Authority to market and sell the Product in such country or jurisdiction.

1.27 "**Regulatory Authority**" means any governmental agency or authority responsible for granting Regulatory Approvals for the Product in the Territory.

1.28 "**Regulatory Filings**" means, with respect to the Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, NDA/BLA, any submission to a regulatory advisory board, any marketing authorization application, and any supplement or amendment thereto.

1.29 "**Royalty Term**" means, with respect to the Product in each country in the Territory, the period commencing on the date of First Commercial Sale in any country within the Territory and expiring upon the later of: (a) five (5) years after the First Commercial Sale; (b) the expiration of all regulatory or data exclusivity for the Product in such country; and, (c) the expiration or abandonment of the last

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Valid Claim of the Licensed Patents, including any patent term extensions or supplemental protection certificates, in such country in the Territory.

1.30 "**Territory**" means the entire world.

1.31 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.32 "**Use**" means to make, have made, use, have used, Develop, have Developed, Commercialize, have Commercialized, import and otherwise exploit.

1.33 "**Valid Claim**" means either: (a) a claim of an issued and unexpired patent included within the Licensed Patents, which has not been permanently revoked or declared unenforceable or invalid by an unreserved and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (b) a claim of a pending patent application included within the Licensed Patents, which claim was filed in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

2. LICENSE GRANT

2.1 **License Grant of Licensed Patents and Licensed Data**. Subject to the terms and conditions of this Agreement, PFIZER hereby grants to LICENSEE (a) an exclusive, with the right to sublicense in accordance with Section 2.5, royalty-bearing right and license under the Licensed Patents to Use the Product within the Territory and (b) a non-exclusive royalty bearing right and license to use the Licensed Data for the sole purpose of the Use of the Product within the Territory.

2.2 **Retained Rights**. LICENSEE acknowledges and agrees that PFIZER retains the right to make, have made, use and import the Product solely for internal research purposes.

2.3 **Residuals**. PFIZER may use for any purpose the Residuals resulting from access to or work with the Product and Licensed Data. As used herein, "**Residuals**" means information in non-tangible form which may be retained by persons who have had access to the Product and Licensed Data, including ideas, concepts or techniques contained therein.

2.4 **No Additional Rights**. Nothing in this Agreement shall be construed to confer any rights upon LICENSEE by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of PFIZER or its Affiliates other than the Licensed Technology, regardless of whether such technology or Intellectual Property Rights shall be dominant or subordinate to any Licensed Patents.

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2.5 **Sublicenses.** LICENSEE shall have the right to sublicense its rights hereunder to any of its Affiliates without PFIZER's approval or to any Third Party upon PFIZER's prior written approval, which approval shall not be unreasonably withheld or delayed. Any and all sublicenses shall be subject to the following requirements:

2.5.1 LICENSEE shall furnish to PFIZER a true and complete copy of each sublicense agreement and each amendment thereto, within thirty (30) days after the sublicense or amendment has been executed.

2.5.2 Each sublicense granted by LICENSEE under this Agreement shall be subject to and consistent with the terms of this Agreement and shall: (a) preclude the assignment of such sublicense without prior written approval of PFIZER, (b) include PFIZER as a third party beneficiary under the sublicense with the right to enforce the terms of such sublicense, (c) preclude the granting of further sublicenses in contravention with the terms of this Agreement, and (d) provide for its termination upon termination of this Agreement.

3. TRANSFER OF DOCUMENTATION

3.1 Under the Original Agreement, PFIZER agreed to maintain its then existing records relating to the Licensed Patents and Products, including regulatory records, for a period of six (6) months from April 16, 2011. LICENSEE acknowledges that PFIZER has fulfilled this obligation and has no further obligation to maintain such records. In the event that the LICENSEE wishes to access these historical records, and to the extent PFIZER still possesses such records, LICENSEE may request that PFIZER make such records available to LICENSEE at the LICENSEE's costs. If PFIZER, in its sole discretion, chooses to fulfill such request, LICENSEE shall pay to PFIZER [*] for each full day or partial day required for a PFIZER employee or contractor to fulfill such request.

4. DEVELOPMENT AND COMMERCIALIZATION

4.1 **Development**. LICENSEE shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop the Product in the Territory. In connection with its efforts to Develop the Product, LICENSEE shall bear all responsibility and expense for filing Regulatory Filings in LICENSEE's name and obtaining Regulatory Approval for the Product. LICENSEE will undertake such activities at its sole expense and shall provide to PFIZER reports regarding LICENSEE's progress within thirty (30) days following the expiration of each Calendar Year.

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4.2 **Commercialization**. LICENSEE shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize the Product in the Territory. LICENSEE will undertake such activities at its sole expense. It is expressly clarified that the LICENSEE shall be solely liable to meet or execute any and all compliances related to the manufacture, distribution or sale of the Products.

4.3 **Payment Terms**.

4.3.1 In consideration of the licenses and rights granted to LICENSEE hereunder, LICENSEE shall pay to PFIZER payments in the following manner:

4.3.2 In partial consideration for the rights granted by PFIZER, the LICENSEE previously issued PFIZER 2,106,103 shares of Common Stock (the "**Shares**"). The Parties acknowledge and agree that the Shares constitute the full amount of the Stock Consideration (as defined in the Original Agreement) PFIZER was entitled to receive under the Original Agreement.

4.3.3 **Milestone Payments**. In further consideration for the licenses and rights granted to LICENSEE hereunder, LICENSEE shall pay to PFIZER the milestone payments set forth below within thirty (30) days after the first achievement of the corresponding milestone (each a "**Milestone Payment**").

(a) **Regulatory Milestones for Product**. LICENSEE shall pay to PFIZER a one-time, non-refundable, non-creditable payment upon the achievement of the following regulatory milestone events (each a "**Regulatory Milestone Event**"). For clarity, the Milestone Payment amount for each Regulatory Milestone Event is payable to PFIZER only once (regardless of the number of Products developed or commercialized, number of approved indications for the Products, or any other event).

Regulatory Milestone Event	Milestone Payment
Date of NDA/BLA submission in the first country in the Territory	US$[*]
Date of receipt of Regulatory Approval in the United States	US$[*]
Date of receipt of Regulatory Approval in first EU country (including, for the avoidance of doubt, the United Kingdom)	US$[*]
Date of receipt of Regulatory Approval in Japan	US$[*]
One year anniversary of the first received Regulatory Approval in the first country in the Territory	US$[*]

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(b) **Sales Milestones**. LICENSEE shall pay to PFIZER a one-time, non-refundable, non-creditable payment upon the first achievement of Net Sales of the Products as set forth in the table below ("**Net Sales Milestone Event**"). For clarity, the Milestone Payment amount for each Net Sales Milestone Event is payable to PFIZER only once (regardless of the number of Products developed or commercialized, number of approved indications for the Products, or any other event):

Net Sales Milestone Event	Milestone Payment
Cumulative Net Sales since First Commercial Sale greater than US$[*]	US$[*]
Cumulative Net Sales since First Commercial Sale greater than US$[*]	US$[*]
Cumulative Net Sales since First Commercial Sale greater than US$[*]	US$[*]
Cumulative Net Sales since First Commercial Sale greater than US$[*]	US$[*]

As set forth above, any Milestone Payment payable by LICENSEE pursuant to this Section 4.3.3 shall be made no more than once with respect to the achievement of each such milestone event.

4.3.4 **Royalty Payments**.

(a) In consideration of the licenses and rights granted to the LICENSEE hereunder, LICENSEE shall pay to PFIZER the royalties set forth below on Net Sales of the Product in the Territory in a Calendar Year by LICENSEE, its Affiliates, and/or its sublicensees, at the applicable royalty rate set forth below (collectively, the "**Royalties**").

Net Sales of Products by LICENSEE and/or its Affiliates or sublicensees in any Calendar Year	Royalty Rate
Portion of Net Sales of Products which are less than US $[*]	[*]% of Net Sales
Portion of Net Sales of Products which are equal to and greater than US $[*] but less than US $[*]	[*]% of Net Sales
Portion of Net Sales of Products which are equal to and greater than US $[*]	[*]% of Net Sales

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(b) LICENSEE shall pay to PFIZER the applicable Royalties within thirty (30) days following the expiration of each Calendar Quarter after the date of the First Commercial Sale. Royalties will be payable on a country-by-country basis commencing as of the First Commercial Sale of a Product in each country until the expiration of the Royalty Term for such Product in each country.

(c) All payments shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation of Net Sales of Product (including all deductions between gross sales and Net Sales) and all Royalties payable to PFIZER for the applicable Calendar Quarter (including any foreign exchange rates employed).

(d) The Royalties shall be payable for the duration of the Royalty Term. It is expressly clarified that any Net Sales by LICENSEE's Affiliate or sublicensee shall be valued and included for the purposes of computing and ascertaining the Milestone Payments and the Royalties that shall be payable to PFIZER and that any NDA/BLA submission or Regulatory Approval by LICENSEE's Affiliate or sublicensee could trigger a Milestone Payment.

4.3.5 **Other Payments**. LICENSEE shall pay to PFIZER any other amounts due under this Agreement within thirty (30) days following receipt of invoice.

4.3.6 **Late Payments**. Any late payments shall bear interest, to the extent permitted by law, at [*] on the date payment is due.

4.3.7 **Payment Forecasts**. At least ninety (90) days prior to the start of each Calendar Year, LICENSEE shall provide to PFIZER a non-binding three (3) year forecast of payments that are anticipated to be made to PFIZER pursuant to this Section 4, which shall be reported on a Calendar Quarter basis for the first year and on a Calendar Year basis for the second and third years.

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4.3.8 **Generic Competition**. In the event a Generic Product is sold by a Third Party in a given country where a Product is sold by LICENSEE (directly or through an Affiliate or Third Party sublicensee) during the Royalty Term following the expiration or abandonment of the last Valid Claim of the Licensed Patents, including any patent term extensions or supplemental protection certificates, in such country in the Territory, and only if and for the duration that Generic Erosion persists for such Product in such country, the applicable royalty rate for such country under Section 4.3.4(a) shall be reduced by [*].

4.4 **Payment Method**.

4.4.1 Any payments under this Section 4 that are recorded in currencies other than the US Dollar shall be converted into US Dollars at the average of the daily foreign exchange rates published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the Calendar Quarter in which such payments or expenses occurred, or for periods less than a Calendar Quarter, the average of the daily rates published in the Wall Street Journal for such period.

4.4.2 All payments from LICENSEE to PFIZER shall be made by wire transfer in US Dollars to the credit of such bank account as may be designated by PFIZER in writing to LICENSEE. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

4.5 **Taxes**.

4.5.1 It is understood and agreed between the Parties that any amounts payable by LICENSEE to PFIZER hereunder are exclusive of any and all applicable sales, use, VAT, GST, excise, property, and other taxes, levies, duties or fees (collectively, "**Taxes**"). LICENSEE shall be responsible for billing and collection from its customers and remitting to the appropriate taxing authority any and all Taxes which it is required to collect or remit. Each Party will be responsible for their own income and property Taxes.

4.5.2 If LICENSEE is required to make a payment to PFIZER subject to a deduction of tax or withholding tax (a "**Withholding Tax Requirement**"), then the sum payable by LICENSEE (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that PFIZER receives a sum equal to the sum which it would have received had no such Withholding Tax Requirement been applicable, and the amount required to be deducted or withheld shall be remitted by LICENSEE in accordance with

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Applicable Law. Any such withholding taxes required under Applicable Law to be paid or withheld shall be an expense of, and borne solely by, LICENSEE.

4.5.3 The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made by LICENSEE to PFIZER under this Agreement.

5. RECORDS; AUDIT RIGHTS

5.1 Relevant Records.

5.1.1 **Relevant Records**. LICENSEE shall maintain accurate financial books and records pertaining to LICENSEE's sale of the Product, including any and all calculations of the applicable Net Sales as well as reports received from sublicensees (collectively, "**Relevant Records**"). LICENSEE shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) three (3) years following expiration or termination of this Agreement.

5.1.2 **Audit Request**. PFIZER shall have the right during the term of this Agreement and for twelve (12) months thereafter to engage, at its own expense, an independent, certified public accountant auditor (for the purposes of this Section 5.1.2, the "**Auditor**") reasonably acceptable to LICENSEE, which acceptance will not be unreasonably withheld or delayed, at reasonable times and upon reasonable notice, to audit or inspect those books or records as the Auditor deems necessary or appropriate for the purpose of verifying the calculation and reporting of Net Sales for the sole purpose of verifying (a) the amount and calculation of Net Sales and royalties and milestones payable with respect to such Net Sales, (b) the withholding taxes, if any, required by Applicable Laws to be deducted as a payment by LICENSEE or its Affiliates or sublicensees in respect of such Net Sales and (c) the exchange rates used in determining the amount of United States Dollars. As a condition to examining any records of LICENSEE or its Affiliates or sublicensees, the Auditor will sign a nondisclosure agreement reasonably acceptable to LICENSEE in form and substance, and shall not disclose to PFIZER, its Affiliates or any Third Party any information that is LICENSEE's or its Affiliate's or sublicensee's confidential customer information regarding pricing or other competitively sensitive proprietary information. Any and all records examined by the Auditor will be deemed LICENSEE's Confidential Information. The Auditor shall disclose to PFIZER only the amount and accuracy of calculations and payments reported and actually

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paid or otherwise payable under this Agreement. The Auditor shall send a copy of the report to LICENSEE at the same time it is sent to PFIZER. Such inspections may be made no more than once each Calendar Year (unless a previous audit resulted in a variation or error resulting in LICENSEE having to bear the costs of such audit, in which event the frequency may occur twice each Calendar Year) and during normal business hours. Such records for any particular Calendar Year shall be subject to no more than one inspection unless the deficiency payment required under Section 5.1.4 has not occurred for such Calendar Year.

5.1.3 **Audit Fees and Expenses**. PFIZER shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment by LICENSEE of more than [*] as to the period subject to the audit, LICENSEE shall reimburse PFIZER for any reasonable and documented out-of-pocket costs and expenses of the audit within thirty (30) days after receiving invoices thereof.

5.1.4 **Payment of Deficiency**. If any audit establishes that LICENSEE underpaid any amounts due to PFIZER under this Agreement, then LICENSEE shall pay PFIZER any such deficiency within thirty (30) days after receipt of written notice thereof. For the avoidance of doubt, such payment will be considered a late payment, subject to section 4.3.6.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 **Pre-existing IP**. Subject to the rights and licenses granted pursuant to this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to or independent of this Agreement.

6.2 **Developed IP**. LICENSEE shall own all rights, title and interests in and to any Intellectual Property Rights that are both: (a) related to the Product, including but not limited to, its Use or its synthesis, and (b) conceived solely by LICENSEE, its Affiliates or sublicensees following April 16, 2011 (collectively, "**Developed IP**").

6.3 **Patent Prosecution**.

(a) **Patent Prosecution and Maintenance**. Subject to PFIZER's rights set forth below, LICENSEE will be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions and the like) and maintaining the Licensed Patents in the Territory (and in PFIZER's name) at

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LICENSEE's own cost and expense. LICENSEE will select qualified patent counsel and corresponding foreign associates to prepare, file, prosecute and maintain the Licensed Patents. LICENSEE will keep PFIZER reasonably informed of the status of the Licensed Patents by timely providing PFIZER copies of significant communications relating to such Licensed Patents that are received from any patent office, patent counsel of record or foreign associate.

(b) **Assistance**. As reasonably requested by PFIZER in writing, LICENSEE shall seek patent term restoration at LICENSEE'S expense (including, but not limited to, the Drug Price Competition and Patent Term Restoration Act), supplementary protection certificates or their equivalents, or patent term extensions with respect to the Licensed Patents in the United States, Japan and Europe.

(c) **Failure to Prosecute or Maintain**. In the event LICENSEE elects to forgo filing, prosecution or maintenance of any of the Licensed Patents, LICENSEE shall notify PFIZER of such election at least forty-five (45) days prior to any filing or payment due date, or any other due date that requires action ("**Election Notice**"). Upon receipt of an Election Notice, PFIZER shall be entitled, upon written notice to LICENSEE, at its sole discretion and expense, to file or to continue the prosecution or maintenance of such Licensed Patents in such country in PFIZER's name using counsel of its own choice and at its own expense ("**PFIZER Patent Rights**"), in which case, the term "**Licensed Patents**" shall be modified to exclude the PFIZER Patent Rights stated in the Election Notice as of the date LICENSEE provides PFIZER such Election Notice.

7. INFRINGEMENT; MISAPPROPRIATION

7.1 **Notification**. Each Party will promptly notify the other Party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Technology in the Territory of which it becomes aware ("**Third Party Infringement**").

7.2 **Infringement Action**.

7.2.1 **Right of First Enforcement**.

(a) LICENSEE shall have the first right (but not the obligation), at

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its own expense, to control enforcement of the Licensed Technology against any Third Party Infringement. Prior to commencing any such action, LICENSEE shall consult with PFIZER and shall give due consideration to PFIZER's recommendations regarding the proposed action. At LICENSEE'S reasonable request, PFIZER will in good faith consider joining LICENSEE as a co-party in any litigation related to the enforcement of the Licensed Technology against any Third Party Infringement. LICENSEE shall give PFIZER timely notice of any proposed settlement of any such action instituted by LICENSEE and shall not, without the prior written consent of PFIZER, enter into any settlement that would: (i) adversely affect the validity, enforceability or scope of any of the Licensed Technology, (ii) give rise to liability of PFIZER or its Affiliates, (iii) admit Third Party non-infringement of any Licensed Technology, or (iv) otherwise impair PFIZER's rights in any Licensed Technology or under this Agreement.

(b) If LICENSEE does not obtain agreement from the alleged infringer to desist or fails to initiate an infringement action within: (i) sixty (60) days following LICENSEE's receipt of notice of the alleged infringement, or (ii) thirty (30) days before the expiration date for filing such actions, whichever comes first, PFIZER shall have the right, at its sole discretion, to control such enforcement of the Licensed Technology at its sole expense.

7.2.2 **Recoveries.** Any recoveries resulting from an action relating to a claim of Third Party Infringement shall first be applied equally against payment of each Party's costs and expenses incurred in connection therewith. Any remaining recoveries shall be retained by (or if received by PFIZER, paid to) LICENSEE; provided, however, PFIZER shall be entitled to a Royalty on such remaining recoveries at the applicable rate set forth herein as if the amount of such remaining recoveries were Net Sales of LICENSEE in the Calendar Year in which the recoveries were received by LICENSEE. If LICENSEE fails to institute an action or proceeding and PFIZER exercises its right to prosecute such infringement, any remaining recoveries shall be retained by PFIZER.

8. CONFIDENTIALITY

8.1 **Definition**. "**Confidential Information**" means the terms and provisions of this Agreement and other proprietary information and data of a financial, commercial or technical nature that the disclosing Party or any of its Affiliates has supplied or

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otherwise made available to the other Party or its Affiliates, which are: (a) disclosed in writing or (b) if disclosed orally, summarized in writing and provided to the receiving Party after disclosure. All Licensed Data shall be considered PFIZER's Confidential Information. Any invention, discovery, development, data, information, process, method, technique or other know-how, whether or not patentable, developed by LICENSEE shall be the Confidential Information of LICENSEE.

8.2 **Obligations**. The receiving Party will protect all Confidential Information against unauthorized disclosure to Third Parties with a reasonable degree of care. The receiving Party may disclose the Confidential Information to its Affiliates, and their respective directors, officers, employees, subcontractors, sublicensees, consultants, attorneys, accountants, banks and investors (collectively, "**Recipients**") who have a need to know such information for purposes related to this Agreement, provided that the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

8.3 **Exceptions**.

8.3.1 The obligations under this Section 8 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party;

(c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

8.3.2 The restrictions set forth in this Section 8 shall not apply to any Confidential Information that the receiving Party is required to disclose under Applicable Laws or a court order or other governmental order,

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provided that the receiving Party: (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure and (c) if the disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel.

8.3.3 In the event that PFIZER wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, PFIZER may disclose to a Third Party Confidential Information of LICENSEE in connection with any such proposed assignment, provided that PFIZER shall hold such Third Party to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

8.4 **Permitted Disclosures**. Notwithstanding the provisions of this Section 8, after providing notice to the other Party and an opportunity to comment, each Party may disclose Confidential Information belonging to the other Party (including the terms of this Agreement) as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary to fulfill its obligations or exercise its rights under this Agreement, including in the following instances:

8.4.1 filing or prosecuting patent applications related to the Product;

8.4.2 defending patents related to the Product;

8.4.3 facilitating the issuance of Regulatory Approvals for the Product;

8.4.4 complying with applicable court orders or governmental regulations;

8.4.5 to receiving Party's directors, officers, employees, consultants, advisors and agents, and with respect to LICENSEE, any contract sales organization it engages to promote the Product, as may be reasonably necessary or appropriate for the receiving Party to satisfy its obligations under this Agreement;

8.4.6 in the case of LICENSEE, disclosure to actual or potential sublicensees, provided, in each case, that any such sublicensee has agreed in writing to be bound by obligations of confidentiality and non-use at least as stringent as those set forth in this Section 8, and that the Confidential Information so disclosed shall remain subject to this Section 8; and

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8.4.7 disclosure to Third Parties in connection with due diligence or similar investigations by or on behalf of a Third Party in connection with a potential license to, distribution agreement with or collaboration with such Third Party (including entry into any such agreement), or a potential merger or acquisition by such Third Party, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by similar terms of confidentiality and non-use at least as stringent as those set forth in this Section 8.

8.5 **Right to Injunctive Relief**. Each receiving Party hereunder agrees that breaches of this Section 8 by such receiving Party may cause irreparable harm to the disclosing Party and shall entitle the disclosing Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

8.6 **Ongoing Obligation for Confidentiality**. Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one copy which may be retained in its confidential files for archive purposes.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 **Representations and Warranties by Each Party**. Each Party represents and warrants to the other Party as of the Effective Date that:

9.1.1 it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

9.1.2 it has full corporate power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

9.1.3 this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

9.1.4 all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

9.1.5 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and

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the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

9.2 **Representations and Warranties by LICENSEE**.

9.2.1 LICENSEE represents and warrants that as of the Effective Date it has the financial and commercial capabilities to Develop and Commercialize the Product in accordance with this Agreement for the 12-month period after the Effective Date.

9.2.2 LICENSEE represents and warrants to PFIZER that it shall comply with all Applicable Law with respect to the performance of its obligations hereunder.

9.2.3 Without limiting the generality contained herein, LICENSEE shall comply with the U.S. Foreign Corrupt Practices Act of 1977 (as modified or amended). LICENSEE represents and warrants that it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence any Government Official. If LICENSEE is itself a Government Official, LICENSEE represents and warrants that it has not accepted, and will not accept in the future, such a payment or transfer. As used herein, "**Governmental Official**" means: (a) any elected or appointed government official *(e.g.*, a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function, (c) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office, (d) an employee or person acting for or on behalf of a public international organization, or (e) any person otherwise categorized as a government official under local law. "**Government**" is meant to include all levels and subdivisions of non-U.S. governments *(i.e.*, local, regional, or national and administrative, legislative, or executive). LICENSEE will update these warranties if it or any of its employees, or a relative of such an individual, becomes a Government Official, or if a Government or Government Official becomes an owner of LICENSEE.

9.3 **No Other Warranties**. EXCEPT AS EXPRESSLY STATED HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO

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WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OF THE PRODUCT. ANY INFORMATION PROVIDED BY PFIZER OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

10. INDEMNIFICATION

10.1 **Indemnification by LICENSEE**. LICENSEE agrees to indemnify, hold harmless and defend PFIZER and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns (each, a "**Pfizer Indemnitee**"), from and against any Claims arising or resulting from: (a) the Development of a Product by LICENSEE, its Affiliates, subcontractors or sublicensees (b) the Commercialization of a Product by LICENSEE, its Affiliates, subcontractors or sublicensees, (c) the negligence, recklessness or wrongful intentional acts or omissions of LICENSEE, its Affiliates, subcontractors or sublicensees, (d) breach by LICENSEE of any representation, warranty or covenant as set forth in this Agreement or (e) breach by LICENSEE of the scope of the license set forth in this Agreement, except to the extent such Claims arise from the breach of this Agreement of, or the negligence or willful misconduct of, any Pfizer Indemnitee. As used herein, "**Claims**" means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees).

10.2 **Indemnification Procedure**. In connection with any Claim for which PFIZER seeks indemnification from LICENSEE pursuant to this Agreement, PFIZER shall: (a) give LICENSEE prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve LICENSEE from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with LICENSEE, at LICENSEE's expense, in connection with the defense and settlement of the Claim; and (c) permit LICENSEE to control the defense and settlement of the Claim; provided, however, that LICENSEE may not settle the Claim without PFIZER's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts PFIZER's rights or obligations. Further, PFIZER shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

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11. **LIMITATION OF LIABILITY**

Consequential Damages Waiver. EXCEPT FOR A BREACH OF SECTION 8 OR OBLIGATIONS ARISING UNDER SECTION 10, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

12. **TERM; TERMINATION**

12.1 **Term**. The term of this Agreement shall commence as of the Effective Date and shall expire upon the last-to-expire Royalty Term. Upon expiration (but not an earlier termination) of this Agreement with respect to a Product, LICENSEE shall have a perpetual, exclusive, fully paid-up, royalty-free license under the Licensed Technology to Use the Product within the Territory.

12.2 **Termination for Cause**. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party breaches any of its material obligations hereunder and fails to cure such breach within thirty (30) days of receiving notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such thirty (30) day period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed sixty (60) days. Any termination by a Party under this Section 12.2 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. For the avoidance of doubt, LICENSEE's failure to use Commercially Reasonable Efforts to Develop or Commercialize the Product shall constitute a material breach by LICENSEE under this Agreement.

12.3 **Termination for a Bankruptcy Event**. Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within ninety (90) days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (c) the institution

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of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of a Party's assets, or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

12.4 **Termination by PFIZER**.

12.4.1 PFIZER shall have the right to immediately terminate this Agreement at any time after the Effective Date in its entirety or on a country-by-country basis in the event LICENSEE or any of its Affiliates or its or their sublicensees contests, challenges, supports or assists any Third Party to contest or challenge, in any patent office, court, regulatory agency or other forum, PFIZER's ownership of or rights in, or the validity, enforceability or scope of, any of the Licensed Patents.

12.4.2 PFIZER shall have the right to immediately terminate this Agreement in the event LICENSEE or its Affiliate or sublicensee fails to achieve the First Commercial Sale in at least one country in the Territory by April 16, 2024.

12.5 **Termination for Convenience**. LICENSEE shall have the right to terminate this Agreement for convenience upon ninety (90) days prior written notice to PFIZER. In the event LICENSEE terminates for convenience, LICENSEE shall pay to PFIZER an early termination fee in an amount equal to [*].

12.6 **Effect of Termination or Expiration**.

12.6.1 Upon termination or expiration of this Agreement, LICENSEE shall pay to PFIZER all amounts due to PFIZER as of the effective date of termination or expiration within thirty (30) days following the effective date of termination or expiration.

12.6.2 Upon termination of this Agreement, LICENSEE shall have the right to sell its remaining inventory of Product following the termination of this Agreement so long as LICENSEE has fully paid any and all Royalties and Milestone Payments owed to PFIZER, and LICENSEE otherwise is not in material breach of this Agreement.

12.6.3 Subject to this Section 12, upon termination of this Agreement, all licenses granted by PFIZER to LICENSEE shall terminate. For clarity, termination of the licenses granted by PFIZER to LICENSEE shall terminate all sublicenses granted by LICENSEE hereunder.

Upon termination of this Agreement by PFIZER pursuant to Section 12.2 (as a result of LICENSEE's breach of its payment obligations under this

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Agreement, including but not limited to, Section 4.3.3 or Section 4.3.4), Section 12.3 or Section 12.4:

(a) LICENSEE hereby grants to PFIZER a non-exclusive, fully paid-up, royalty-free, worldwide, transferable, perpetual and irrevocable license, with the right to sublicense, to Use any Intellectual Property Rights Controlled by LICENSEE that arise from the Development or Commercialization of the Product, including without limitation, any and all Developed IP for Use of the Product.

(b) To the extent permitted by applicable Regulatory Authorities, LICENSEE shall (i) transfer to PFIZER all Regulatory Filings and Regulatory Approvals held by LICENSEE with respect to the Product, and (ii) to the extent subsection (i) is not permitted by the applicable Regulatory Authority, permit PFIZER to cross-reference and rely upon any Regulatory Approvals and Regulatory Filings filed by LICENSEE with respect to the Product.

(c) LICENSEE hereby grants to PFIZER a fully paid-up, royalty-free, worldwide, transferable, sub-licensable, perpetual and irrevocable license to use the Trademarks identifying a Product for the purpose of manufacturing, marketing, distributing and selling the Product. As used herein, "**Trademarks**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

(d) Upon PFIZER's request, LICENSEE shall continue all on-going Development for a mutually agreed upon migration period after termination of this Agreement, which period shall not be less than six (6) months unless otherwise agreed to by the Parties ("**Migration Period**"). During the Migration Period, LICENSEE shall provide such knowledge transfer and other training to PFIZER or its Affiliates or a Third Party that is designated in writing by PFIZER ("**Designated Affiliate/Third Party**") as reasonably necessary for PFIZER or the Designated Affiliate/Third Party to continue such activities. In connection with such transfer, LICENSEE shall, at PFIZER's option: (i) transfer to PFIZER or the Designated Affiliate/Third Party all Product at the cost paid by LICENSEE to manufacture such Product, (ii) transfer to PFIZER or the Designated Affiliate/Third Party all Licensee Inventory owned by

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LICENSEE at the cost paid by LICENSEE for such Licensee Inventory, and (iii) assign to PFIZER or the Designated Affiliate/Third Party any agreements with Third Parties with respect to the Development or Commercialization of the Product. As used herein, "**Licensee Inventory**" means all components and works in process produced or held by LICENSEE with respect to the manufacture of Products.

12.7 **Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 5, 6.1, 8, 10, 11, 12.6, 14, 15, 16.3 and 16.8 shall survive expiration or termination of this Agreement.

13. PUBLICITY

13.1 **Publicity**.

13.1.1 Subject to PFIZER's rights herein, neither Party (nor any of its Affiliates or agents) shall use the name or trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure, including, with respect to LICENSEE and its representatives, references to prior affiliation with or employment by PFIZER, without the prior written consent of the other Party in each instance.

13.1.2 Except as required by Applicable Law (including, disclosure requirements of the U.S. Securities and Exchange Commission ("**SEC**"), the NASDAQ stock exchange or any other stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text; provided, however, that the Party making such announcement shall make every effort not to disclose any of the other Party's Confidential Information.

13.1.3 The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency on which

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securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided, however, that each Party shall ultimately retain control over what information it must disclose to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency, as the case may be, and provided, further, that the Parties shall use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies and shall make every effort not to disclose any of the other Party's Confidential Information. Other than such obligation, neither Party (nor its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency.

14. LICENSEE INSURANCE

14.1 **Insurance Requirements**. LICENSEE will maintain during the term of this Agreement and until the later of: (a) three (3) years after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Product have expired, commercial general liability insurance from a minimum "A-" A.M. Best-rated insurance company, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than [*] per occurrence and [*] in the aggregate. LICENSEE has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on LICENSEE's liability hereunder. Such policies shall name PFIZER and its Affiliates as additional insured and provide a waiver of subrogation in favor of PFIZER and its Affiliates. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to PFIZER or its Affiliates. Any deductibles for such insurance shall be assumed by LICENSEE.

14.2 **Policy Notification**. LICENSEE shall provide PFIZER with certified copies of such policies or original certificates of insurance evidencing such insurance: (a) prior to execution by both Parties of this Agreement, and (b) prior to expiration of any one coverage. Such certificates shall provide that PFIZER shall be given at least thirty (30) days written notice prior to cancellation, termination or any change to restrict the coverage or reduce the limits afforded.

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15. **DISPUTE RESOLUTION**

15.1 **General**. Except for disputes for which injunctive or other equitable relief is sought to prevent the unauthorized use or disclosure of proprietary materials or information or prevent the infringement or misappropriation of a Party's Intellectual Property Rights, the following procedures shall be used to resolve any dispute arising out of or in connection with this Agreement:

15.2 **Meeting**. Promptly after the written request of either Party, each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute. If the designated representatives do not resolve the dispute within sixty (60) Business Days of such request, then an executive officer of each Party shall meet in person or by telephone to review and attempt to resolve the dispute in good faith. The executive officers shall have sixty (60) Business Days to attempt to resolve the dispute.

16. **GENERAL PROVISIONS**

16.1 **Assignment**. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) PFIZER may assign to a Third Party its rights to receive some or all of the fees payable hereunder, (b) each Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (c) either Party may assign this Agreement in the event of a Change in Control. As used herein, "**Change in Control**" means the acquisition of a Party by a Third Party or the sale of all or substantially all of its business to which this Agreement relates. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.

16.2 **Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefore which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

16.3 **Governing Law; Exclusive Jurisdiction**.

16.3.1 This Agreement shall be governed by and construed under the laws in effect in the State of New York, US, without giving effect to any conflicts

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of laws provision thereof or of any other jurisdiction that would produce a contrary result.

16.3.2 The courts of New York shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum; and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award.

16.4 **Force Majeure**. Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a "**Force Majeure Event**"), provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for one hundred eighty (180) days or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

16.5 **Waivers and Amendments**. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

16.6 **Relationship of the Parties**. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between PFIZER and LICENSEE, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement

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shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

16.7 **Successors and Assigns**. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

16.8 **Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (receipt requested); or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to PFIZER:

Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: General Counsel

With a copy to:

LegalNotice@pfizer.com

If to LICENSEE:

Gemphire Therapeutics Inc.
17199 N. Laurel Park Dr., Suite 401
Livonia, MI 48152
Fax: 248-671-0500
Attention: President and CEO

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With a copy to:

Honigman Miller Schwartz and Cohn LLP
660 Woodward Avenue
2290 First National Building
Detroit, Michigan 48226-3506
Telephone: (269) 337-7702
Fax: (269) 337-7703
Email: ptorrence@honigman.com
Attention: Phillip D. Torrence, Esq.

16.9 **Further Assurances**. LICENSEE and PFIZER hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

16.10 **No Third Party Beneficiary Rights**. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

16.11 **Entire Agreement; Confidentiality Agreement**.

(a) This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, without limitation, the Original Agreement and that certain Confidentiality Agreement by and between the Parties, dated October 28, 2008 and amendment dated January 29, 2009 ("**CDA**"). The Parties acknowledge and agree that, as of the Effective Date, this Agreement shall supersede the Original Agreement, which is terminated in its entirety.

(b) In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

16.12 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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16.13 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

16.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

[Signatures on next page]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

GEMPHIRE THERAPEUTICS INC.	**PFIZER INC.**
By: /s/ Steven Gullans	By: /s/ Mark Avagliano
Name: Steven Gullans	Name: Mark Avagliano
Title: CEO	Title: VP, Corporate Development

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SCHEDULE A: LICENSED PATENTS

1. PATENTS

Docket Number	Former Dkt No	Country	Application Number	Application Date	Status	Sub Status
[*]	[*]	[*]	[*]	[*]	[*]	[*]

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Gemphire Announces Amended and Restated Gemcabene License Agreement with Pfizer Inc.

LIVONIA, Mich., August 6, 2018 -- Gemphire Therapeutics Inc. (NASDAQ: GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and nonalcoholic steatohepatitis (NASH), today announced that it has amended and restated the license agreement with Pfizer Inc. covering gemcabene.

Gemphire licensed exclusive worldwide commercial rights to gemcabene from Pfizer in an agreement signed in April 2011. Under the original agreement, Pfizer had the right to terminate the license if the drug was not adequately commercialized by April 2021. The amended and restated agreement contains a number of changes to the license, including extending the date of the agreed deadline for the first commercial sale. As amended, Pfizer has the right to terminate the license if the first commercial sale has not occurred by April 2024. The royalty period in countries in which gemcabene becomes approved for commercial sale, if any, has been extended, and the royalty rates that are payable upon achieving certain aggregate sales levels of gemcabene have increased slightly, ranging from the high single digits to the mid-teens depending on the level of net sales, in consideration for such extension.

“We are pleased to enter into this amended and restated agreement with Pfizer that includes provisions that we believe benefit both parties,” said Dr. Steven Gullans, CEO of Gemphire. “The extension to the agreed date by which we need to commercialize gemcabene provides us with additional flexibility to focus on the optimal development path and timeline for gemcabene. Additionally, we believe the extension will remove any near-term considerations by investors and potential strategic partners about our ability to achieve commercialization under the license agreement. Based on our current projections, however, we believe we will be successful in bringing gemcabene to market in at least one of our chosen disease indications well before this date.”

For further details on the amended and restated license agreement, refer to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2018.

Gemcabene’s mechanism of action and safety profile are highly differentiated from other clinical candidates

Gemphire’s product candidate gemcabene is a first-in-class, once-daily, oral therapy that may be suitable for patients who are unable to achieve normal levels of LDL-C or TGs with currently approved therapies, primarily statins. Gemcabene's mechanism of action (MOA) enhances the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibition of the production of cholesterol and TGs in the liver. The combined effect of these mechanisms has been clinically observed to result in a reduction of plasma non-HDL-C, VLDL-C, LDL-C, apolipoprotein B and TGs. In addition, gemcabene has been shown to markedly lower C-reactive protein in humans and improve insulin sensitization. Gemcabene’s MOA is liver-directed involving downregulation of hepatic apolipoprotein C-III (apoC-III) mRNA expression and decrease of plasma apoC-III levels. Gemcabene has also been shown to reduce liver sulfatase-2 mRNA levels, known to be elevated in diabetic and obese patients. Elevated sulfatase-2 is thought to reduce the effectiveness of the liver VLDL-remnant receptor (also known as Syndecan-1), that normally plays a role in removing TG containing particles from the plasma. Gemcabene also reduces acetyl-CoA carboxylase (ACC1) and CCR2/CCR5 receptor mRNA levels, markers involved in the progression of NASH/NAFLD. Gemcabene has demonstrated POC efficacy for NASH in the rodent STAM™ model developed at SMC Laboratories in Tokyo, Japan. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in nearly 1,200 subjects across 25 Phase 1 and Phase 2 clinical trials. Given this profile of efficacy across multiple pathological pathways, as well as

evidence of safety and tolerability, particularly when used as an add-on to many other therapeutic drugs, gemcabene has attributes that support studies in humans for NASH.

About Gemphire
Gemphire is a clinical-stage biopharmaceutical company that is committed to helping patients with cardiometabolic disorders, including dyslipidemia and NASH. The Company is focused on providing new treatment options for cardiometabolic diseases through its complementary, convenient, cost-effective product candidate gemcabene as add-on to the standard of care, especially statins that will benefit patients, physicians, and payors. Gemphire's Phase 2 clinical program is evaluating the efficacy and safety of gemcabene in hypercholesterolemia, including FH and ASCVD, SHTG and NASH/NAFLD. Two trials supporting hypercholesterolemia and one trial in SHTG have been completed under NCT02722408, NCT02634151 and NCT02944383, respectively, and the Company has initiated two proof-of-concept trials for NAFLD/NASH. Please visit www.gemphire.com for more information.

Forward Looking Statements
Any statements in this press release about Gemphire's future expectations, milestones, goals, plans and prospects, including statements about Gemphire's financial prospects, future operations and sufficiency of funds for future operations, clinical development of Gemphire's product candidate, expectations regarding future clinical trials, regulatory submissions and meetings and future expectations and plans and prospects for gemcabene, including the expected timing to bring gemcabene to market in an indication, expectations for the future competitive environment for gemcabene, expectations regarding operating expenses and cash used in operations, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "promising," "targets," "may," "potential," "will," "would," "could," "should," "continue," "scheduled" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: developments in the capital markets, the success and timing of Gemphire's regulatory submissions and pre-clinical and clinical trials; regulatory requirements or developments; changes to Gemphire's clinical trial designs and regulatory pathways; changes in Gemphire's capital resource requirements; the actions of Gemphire's competitors; Gemphire's ability to obtain additional financing; Gemphire's ability to successfully market and distribute its product candidate, if approved; Gemphire's ability to obtain and maintain its intellectual property protection; and other factors discussed in the "Risk Factors" section of Gemphire's annual report and in other filings Gemphire makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Gemphire's views as of the date hereof. Gemphire anticipates that subsequent events and developments will cause Gemphire's views to change. However, while Gemphire may elect to update these forward-looking statements at some point in the future, Gemphire specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Gemphire's views as of any date subsequent to the date hereof.

Contact:
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(617) 535-7742

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Gemphire Therapeutics Inc.
(734) 245-1700