## **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): May 11, 2020

## **AERPIO PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

001-38560 (Commission File Number)

61-1547850 (I.R.S. Employer Identification No.)

9987 Carver Road Cincinnati, OH (Address of principal executive offices)

45242 (Zip Code)

Registrant's telephone number, including area code (513) 985-1920

**Not Applicable** (Former name or former address, if changed since last report)

-	Common stock, \$0.0001 par value per share	ARPO	Nasdag Capital Market		
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered		
Securities registered pursuant to Section 12(b) of the Act:					
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))				
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))				
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)				
	Written communications pursuant to Rule 425 under th	ne Securities Act (17 CFR 230.425)			
	owing provisions:				

Securities Exchange Act of 1934.

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. ⊠

#### Item 1.01 Entry into a Material Definitive Agreement

Aerpio Pharmaceuticals, Inc. (the "Company", "we" or "us") entered into an Amendment No. 1 (the "Amendment") to the License Agreement (the "Agreement") with a wholly-owned subsidiary of Gossamer Bio, Inc. (including its affiliates, "Gossamer"), effective on May 11, 2020, which amended the License Agreement entered into by such parties on June 24, 2018. Pursuant to the Agreement, the Company has granted Gossamer an exclusive, sublicensable license to develop and commercialize AKB-4924 (re-designated GB004) and other structurally related products worldwide. As described in greater detail below, the Amendment modified certain economic terms contained in the original Agreement. The summary below supersedes the description of such certain economic terms of the original Agreement contained in the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 25, 2018 (File No. 000-53057). Other than as modified by the Amendment, all other terms of the original Agreement remain unchanged.

As required by the Amendment, Gossamer made a one-time payment to us of \$15.0 million on the effective date of the Amendment. Under the Agreement, as amended, we are also eligible to receive up to \$40.0 million in approval milestone payments related to indications in ulcerative colitis and Crohn's disease, and up to \$50.0 million in sales milestone payments. Under the Agreement, as amended, we are also eligible to receive tiered royalties on sales of licensed products at percentages ranging from the low to mid single digits, subject to certain customary reductions. In addition, under Section 6.4 of the original Agreement, we may continue to elect, under certain circumstances, in lieu of receiving the foregoing milestone payments and royalties, to receive 20% of the payments received by Gossamer and its stockholders (with some exclusions) in connection with Gossamer's grant of a sublicense or other rights to the licensed products or if Gossamer undergoes a change of control and the value of the transaction exceeds a certain value (provided that Gossamer can prevent the Company from exercising this option if the parent company of Gossamer is the entity undergoing the change of control, in which case each of the royalty rate percentages described above would automatically be increased by low single digits). Conversely, the Company could be required to accept such 20% of those payments, if Gossamer agrees to pay the Company a certain minimum upon Gossamer and its stockholders being paid. Such amount may be reduced if the subject transaction includes pharmaceutical candidates or products or other named asset categories in addition to the licensed products.

The foregoing description of the Amendment is qualified in its entirety by reference to the complete text of the Amendment, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K. The original Agreement was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 25, 2018 (File No. 000-53057).

#### Item 8.01 Other Events

On May 12, 2020, the Company issued a press release announcing its entry into the Amendment. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Evhibit

No.	<u>Description</u>
10.1*	Amendment No. 1 to License Agreement, dated May 11, 2020, by and between Aerpio Pharmaceuticals, Inc. and GB004, Inc.
99.1	Press release issued by Aerpio Pharmaceuticals, Inc., on May 12, 2020.

\* Certain confidential portions of this exhibit (indicated by brackets and asterisks) have been omitted from this exhibit.

## **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 hereunto duly authorized.

Date: May 12, 2020 AERPIO PHARMACEUTICALS, INC.

By: /s/ Joseph Gardner, Ph.D.

Joseph Gardner President and Founder

### AMENDMENT NO. 1 TO LICENSE AGREEMENT

This Amendment No. 1 to License Agreement (this "<u>Amendment</u>"), dated as of May 11, 2020 (but only effective as of the Amendment Effective Date, as defined below), is made by and between Aerpio Pharmaceuticals, Inc., a Delaware corporation having business offices at 9987 Carver Road, Suite 420, Cincinnati, OH 45242 ("<u>Aerpio</u>"), and GB004, Inc., a Delaware corporation having business offices at 3013 Science Park Road, San Diego, CA 92121 ("<u>Licensee</u>"). Aerpio and Licensee are sometimes hereinafter referred to each as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

WHEREAS, Aerpio and Licensee entered into a License Agreement dated as of June 24, 2018 (the "License Agreement"); and

WHEREAS, the Parties desire to make certain amendments to the License Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

- 1. <u>Definitions</u>. Capitalized terms not defined in this Amendment have the meanings given such terms in the License Agreement.
- 2. <u>Payment Upon Amendment Effective Date</u>. Licensee will pay to Aerpio a one-time payment in cash of fifteen million U.S. dollars (\$15,000,000), which payment will be non-refundable and non-creditable and not subject to set-off. This Amendment will go into effect on such date as both (i) the Parties have exchanged their respective signatures to this Amendment and (ii) Aerpio has received such fifteen million dollar payment.
- 3. <u>Amendments</u>. The following amendments will become effective if and when Aerpio receives the payment set forth in the above Section 2.
  - 3.1 Section 1.51 of the License Agreement is hereby amended by adding "to the extent" immediately following "solely" in the first sentence.
  - 3.2 Section 6.2 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"Milestone Payments. As set forth in the following table, Licensee will make the following payments in cash (the "Milestone Payments") to Aerpio upon achievement of each of the milestone events set forth in the tables below (the "Milestone Events") by Licensee or its Affiliates or Sublicensees. Each Milestone Payment will be payable by Licensee to Aerpio within [\*\*\*] ([\*\*\*]) days after the achievement of the corresponding Milestone Event with respect to the first Licensed Product. Such payments will be non-refundable and non-creditable and not subject to set-off."

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[\*\*\*]." SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

"Approval Milestones"

"Milestone Event"

[\*\*\*]

[\*\*\*]

For clarity, each Approval Milestone payment is due only once regardless of the number of Licensed

"Sales Milestones"

Products developed by Licensee.

"Milestone Event" "Milestone Payment"

First achievement of [\*\*\*] of annual Net Sales of all Licensed Products

in the Territory in a particular Calendar Year \$[\*\*\*]

For clarity, such Sales Milestone payment is due only once regardless of the number of Licensed Products commercialized by Licensee or the number of times the Sales Milestone is met.

3.3 Section 6.3(a) of the License Agreement is hereby deleted in its entirety and replaced with the following:

"Royalties. Licensee will pay to Aerpio running royalties in cash at the graduated royalty rates specified in the following table with respect to the aggregate annual worldwide Net Sales of all Licensed Products in a calendar year:

Aggregate Annual Worldwide Net Sales of All Licensed Products in a calendar year	Royalty Rate
Portion of cumulative Calendar Year Net Sales of Licensed Products in the	
Territory up to and including [***]	[***]%
Portion of cumulative Calendar Year Net Sales of Licensed Products in the	
Territory between [***]	[***]%
Portion of cumulative Calendar Year Net Sales of Licensed Products in the	
Territory exceeding [***]	[***]%

The applicable royalty rate will be calculated as provided in this Section 6.3(a) by reference to the aggregate annual worldwide Net Sales of all Licensed Products. By way of example, [\*\*\*]

3.4 Section 6.4(e) of the License Agreement is hereby amended by adding the following clause to the end of the sentence in such Section: ", and provided further that, if Licensee were to send such notice to Aerpio and this Section 6.4 thereby did not apply to such

Change of Control, then the royalty rates set forth in the table in Section 6.3(a) would automatically be increased from [\*\*\*] percent ([\*\*\*]%), [\*\*\*] percent ([\*\*\*]%) and [\*\*\*] percent ([\*\*\*]%), respectively, only for Net Sales invoiced after such Change of Control (and, for clarity, the example below such table would no longer be accurate for those Net Sales), save for the following exclusion of certain Net Sales: those increased [\*\*\*]/[\*\*\*]/\* royalty rates would not apply, and instead the original [\*\*\*]/[\*\*\*]/\* royalty rates would apply, to those Net Sales (and only those Net Sales) invoiced after such Change of Control by any Sublicensee (and its Affiliates) within the scope of a sublicense of commercial rights granted under Section 5.2 to such Sublicensee before such Change of Control, provided that this exclusion shall not apply to any such Sublicensee that is either (i) an Affiliate of Licensee before such Change of Control, or (ii) the acquirer (or an Affiliate of such acquirer) of such ultimate parent in such Change of Control. For the avoidance of doubt, this Section 6.4(e) shall not apply if (1) a Qualifying Transaction has occurred and (2) the Licensee has exercised its option to pay Aerpio the greater of (i) [\*\*\*] (\$[\*\*\*]) or (ii) the 20% Amount of any upfront Transaction Payment pursuant to Section 6.4(c).

4. <u>Press Releases Regarding Execution of the Amendment</u>. The Parties each agree to issue their respective press releases with any language related to this Amendment attached to Exhibit A no earlier than the close of the U.S. market on May 12, 2020.

#### 5. <u>General Provisions</u>.

- 5.1 Effect on License Agreement. Except as specifically amended by this Amendment, the License Agreement will remain in full force and effect and is hereby ratified and confirmed. Each future reference to the License Agreement will refer to the License Agreement as amended by this Amendment. To the extent a conflict arises between the terms of the License Agreement and this Amendment, the terms of this Amendment will prevail but only to the extent necessary to accomplish their intended purpose.
- 5.2 <u>Governing Law</u>. This Amendment will be governed by and construed in accordance with the laws of the State of New York, without regard to its conflicts of law provisions.
- 5.3 <u>Counterparts; Facsimiles or PDF</u>. This Amendment may be executed in one (1) or more counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Facsimile or PDF execution and delivery of this Amendment by either Party will constitute a legal, valid and binding execution and delivery of this Amendment by such Party.

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IN WITNESS WHEREOF, the Parties have caused this Amendment No. 1 to License Agreement to be executed by their respective duly authorized representatives and to become effective as of the Amendment Effective Date.

## AERPIO PHARMACEUTICALS, INC.

By: /s/ Joseph H. Gardner

(Signature)

Name: Joseph H. Gardner, PhD Title: President and Founder

## **GB004, INC.**

By: /s/ Christian Waage

(Signature)

Name: Christian Waage Title: Secretary

# Exhibit A Amendment Press Release Language



## Aerpio Announces Amended Licensing Deal with Gossamer Bio on its Inflammatory Bowel Disease (IBD) Product Candidate GB004 (formerly AKB-4924). Aerpio Received an Immediate Payment of \$15 million.

CINCINNATI — (BUSINESS WIRE) — Aerpio Pharmaceuticals, Inc. ("Aerpio") (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, today announced a restructuring of their licensing deal with a wholly owned subsidiary of Gossamer Bio Inc., GB004, Inc. ("Gossamer Bio") (Nasdaq: GOSS), for its HIF-1 alpha stabilizer, GB004. The terms of the amended agreement include a \$15 million immediate payment to Aerpio and a total of \$90 million in milestone payments related to regulatory approvals and commercial sales. In addition, Aerpio is also eligible to receive tiered royalties on sales of licensed products at percentages ranging from the low to mid-single digits. The deal continues the collaboration between Gossamer Bio's strong gastrointestinal ("GI") development team and Aerpio's management team.

Joseph Gardner, PhD, Aerpio's President and Founder, commented "We are excited about continuing our relationship with Gossamer Bio as they advance GB004 with their experienced team in GI drug development. The renegotiated licensing deal is intended to place Gossamer Bio in a better position to progress GB004, and in addition, is designed to facilitate the further development of each company's respective pipelines." Additional details of the amended agreement are summarized in an 8-K filing dated May 12, 2020.

GB004 is an oral, gut-targeted HIF-1 alpha stabilizer that has been shown to improve disease indices in multiple models of inflammatory bowel disease. "Unlike other HIF stabilizers that mainly affect HIF-2 and stimulate erythropoiesis, GB004 is differentiated in that it preferentially stabilizes HIF-1 alpha which has a profound anti-inflammatory and mucosal healing effect. We believe these properties make it an ideal candidate for the treatment of IBD" said Kevin Peters MD, Aerpio's Chief Scientific Officer.

#### About GB004 (formerly AKB-4924)

GB004, a selective stabilizer HIF-1 alpha, is being developed for the treatment of inflammatory bowel disease. HIF-1 alpha is involved in mucosal wound healing and the reduction of inflammation in the gastrointestinal tract. Gossamer Bio recently completed a Phase 1b study in patients with ulcerative colitis and is planning a Phase 2 study.

#### **About Aerpio Pharmaceuticals**

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications. Recently published mouse

and human genetic data implicate the Angpt/Tie2 pathway in maintenance of Schlemm's canal, a critical component of the conventional outflow tract. The Company's lead compound, razuprotafib (formerly AKB-9778), a first-in-class small molecule inhibitor of vascular endothelial protein tyrosine phosphatase ("VE-PTP"), is being developed as a potential treatment for open angle glaucoma, and the Company intends to investigate the therapeutic potential of razuprotafib in other indications. The Company is also evaluating development options for ARP-1536, a humanized monoclonal antibody, for its therapeutic potential in the treatment of diabetic vascular complications including nephropathy and diabetic macular edema ("DME"). The Company's third asset is a bispecific antibody that binds both VEGF and VE-PTP which is designed to inhibit VEGF activation and activate Tie2. This bispecific antibody has the potential to be an improved treatment for wet age-related macular degeneration and DME via intravitreal injection. Finally, the Company has exclusively out-licensed AKB-4924 (now called GB004), a first-in-class small molecule inhibitor of hypoxia-inducible factor-1 (HIF). GB004 is being developed by AKB-4924's exclusive licensor, Gossamer Bio, Inc. (Nasdaq: GOSS). For more information, please visit www.aerpio.com.

### **Forward Looking Statements**

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the Company's product candidates, including razuprotafib, ARP-1536 and the bispecific antibody asset, the clinical development plan therefor and the therapeutic potential thereof, the Company's strategic alternatives review process and the potential transactions that may be identified and explored as a result of that process, and the intended benefits from its collaboration with Gossamer Bio for GB004, including the continued development of GB004 and the milestone and royalty payments related to the collaboration. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, the continued development of GB004 and maintaining and deriving the intended benefits of the Company's collaboration with Gossamer Bio; ability to continue to develop razuprotafib or other product candidates; the inherent uncertainties associated with the drug development process, including uncertainties in regulatory interactions, the design of planned or future clinical trials, commencing clinical trials and enrollment of patients in clinical trials; the impact of the ongoing COVID-19 pandemic on the Company's business operations, including research and development efforts and the ability of the Company to commence, conduct and complete its planned clinical activities; the ability to identify and consummate strategic alternatives that yield additional value for shareholders; the timing, benefits and outcome of the Company's strategic alternatives review process, including the determination of whether or not to pursue or consummate any strategic alternative; the structure, terms and specific risks and uncertainties associated with any potential strategic transaction; potential disruptions in our business and the stock price as a result of our exploration, review and pursuit of strategic alternatives or the public announcement thereof and any decision or transaction resulting from such review; and competition in the industry in which the Company operates and overall market conditions; and the additional factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, as updated by our subsequent Quarterly Reports on Form 10-Q and our other subsequent filings with the SEC.

These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov.

## Contacts

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Source: Aerpio Pharmaceuticals, Inc.