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): December 19, 2018

Scholar Rock Holding Corporation
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38501**	**82-3750435**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

620 Memorial Drive, 2nd Floor, Cambridge, MA 02139
(Address of Principal Executive Offices) (Zip Code)

(857) 259-3860
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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.

Master Collaboration Agreement

On December 19, 2018, Scholar Rock, Inc. ("Scholar Rock"), a wholly owned subsidiary of Scholar Rock Holding Corporation (the "Company"), entered into a Master Collaboration Agreement (the "Collaboration Agreement") with Gilead Sciences, Inc. ("Gilead") pursuant to which Scholar Rock will conduct research and pre-clinical development activities relating to the diagnosis, treatment, cure, mitigation or prevention of diseases, disorders or conditions, other than in the field of oncology, (as further described in the Collaboration Agreement, the "Field") in accordance with a pre-determined research plan. The goal of the collaboration is to characterize and identify program antibodies (each, a "Program Antibody") that meet the development criteria with respect to three separate programs (each, a "Program"). On a Program-by-Program basis, Gilead has an exclusive option (with respect to each Program, an "Option"), exercisable in its discretion, to enter into a license agreement, as further described below under the heading "*Form of License Agreement*" with Scholar Rock with respect to such Program. Such Option may be exercised by Gilead at any time from December 19, 2018 (the "Effective Date") through a date that is 90 days following the expiration of the Research Collaboration Term (as defined below) for a given Program, or until termination of the Program, whichever is earlier (the "Option Exercise Period"). Scholar Rock and Gilead have agreed to conduct the foregoing activities on an exclusive basis.

Scholar Rock and Gilead will establish a joint steering committee (the "JSC"). The JSC will, among other powers and responsibilities, review, oversee and have decision-making responsibilities for certain activities performed under the Programs, including reviewing and amending the research plans, reviewing any development candidate nominations, selecting a development candidate, and overseeing the strategic direction of the Programs.

Scholar Rock will conduct its activities under the Collaboration Agreement, on a Program-by-Program basis, during the period beginning on the Effective Date and ending on the earliest to occur of (a) the date that the JSC first approves a selected development candidate for such Program, (b) the third anniversary of the Effective Date, or (c) the effective date of termination of the Collaboration Agreement (the "Research Collaboration Term"). During the Research Collaboration Term, for each Program, Scholar Rock will notify Gilead, through the JSC, of up to two Program Antibodies (in the case that Gilead rejects one, in accordance with the terms of the Collaboration Agreement) that satisfy the development criteria for such Program (the "Development Candidate Nomination"). If, at the end of the Research Collaboration Term, Scholar Rock has not notified the JSC of any Program Antibodies that meet the development criteria for a Program and Gilead does not exercise its Option, upon the filing of an Investigational New Drug application by or on behalf of Scholar Rock for an antibody that satisfies certain criteria within a certain period of time following the Option Exercise Period expiration, Gilead will have the right to license such antibody and the related Program.

Pursuant to the Collaboration Agreement, Gilead will make an upfront payment of $50 million and an upfront equity investment of $30 million when the Collaboration Agreement takes effect (as further described under "*Equity Investment*" in this Item 1.01 below). Subject to the terms and conditions set forth in the Collaboration Agreement, Gilead will pay Scholar Rock a one-time milestone payment in the amount of $25 million following achievement of successful demonstration of *in vivo* proof of concept consistent with certain criteria detailed in the Collaboration Agreement. If Scholar Rock does not demonstrate *in vivo* proof of concept within a specified period of time, the parties will reasonably discuss reallocation of Program resources and, subject to mutual written agreement, introducing a new research program into the Collaboration Agreement.

This Collaboration Agreement will remain in effect, on a Program-by-Program basis, until Gilead exercises its Option with respect to a given Program or until expiration of the applicable Option Exercise Period, whichever is earlier (the "Term"). Unless earlier terminated, the Term shall expire in its entirety upon the expiration of the last to expire Option Exercise Period under the Collaboration Agreement.

Either party to the Collaboration Agreement may terminate the Collaboration Agreement (i) on a Program-by-Program basis for the material breach by the other party of its obligations under the Collaboration Agreement, subject to cure rights and (ii) effective immediately upon written notice to the other party if the other party declares bankruptcy. After an indicated period of time following the Effective Date, Gilead may terminate the Collaboration Agreement in its sole discretion and in its entirety or on a Program-by-Program basis, with sufficient prior written notice. Gilead will also be deemed to have terminated the Collaboration Agreement immediately with respect to a Program, without prior notice in the event that Gilead exercises its decision making authority not to approve for the second time a development candidate nomination which satisfies the applicable development criteria as a selected development candidate for such Program. Other termination rights are as specified in the Collaboration Agreement.

The Collaboration Agreement includes various representations, warranties, covenants, dispute escalation and resolution mechanisms, indemnities and other provisions customary for transactions of this nature.

Form of License Agreement

Upon Gilead's exercise of an Option under the Collaboration Agreement, the parties will enter into an agreed form of license for the applicable Program (the "License Agreement"), under which Gilead will be responsible for development and commercialization activities for product candidates arising out of such Program.

Under each License Agreement, Scholar Rock will grant Gilead an exclusive license for the development and commercialization of Licensed Antibodies and Licensed Products in the Field, all as defined in the License Agreement. In addition, the license grants Gilead sole responsibility and decision making authority to conduct all non-clinical studies and trials necessary to obtain regulatory approval for the Licensed Products. Gilead must use commercially reasonable efforts to develop and commercialize Licensed Products, subject to certain specifications.

In partial consideration of the exclusive license granted to Gilead by Scholar Rock, Gilead will make non-refundable and non-creditable, milestone payments upon the first achievement of certain research and development milestone events and certain commercial milestone events with respect to a Licensed Product. The total potential aggregate Option exercise fee, development, regulatory and commercial milestone payments with respect to each Program is $475 million. Additionally, in partial consideration of the rights granted to Gilead pursuant to the License Agreement, Gilead shall pay to Scholar Rock certain tiered royalties at a rate ranging from the high single-digits to the low double-digits (depending on the amount of net sales) on each Licensed Product in a given calendar year, on a country-by-country basis.

This License Agreement will remain in effect, on a Licensed Product-by-Licensed Product basis and country-by-country basis, until the expiration of the royalty term for such Licensed Product in such country (the "License Agreement Term"). Unless earlier terminated, the License Agreement Term shall expire in its entirety upon the expiration of the last to expire royalty term under the License Agreement.

The parties have the right to terminate the License Agreement for the other party's material breach of its obligations under the License Agreement, subject to cure rights. Additionally, Gilead may terminate the License Agreement in its sole discretion and in its entirety or on a Licensed Program-by-Licensed Program basis with sufficient prior written notice. Either party to the License Agreement may terminate the License Agreement if the other party declares bankruptcy. Other termination rights are as specified in the License Agreement. Upon termination, to the extent Gilead grants Scholar Rock an exclusive license to certain intellectual property relating to the Program Antibodies, Gilead will be entitled to royalties for any reversion products based on the stage of development of the reversion products at the time of termination.

The License Agreement includes customary representations and warranties on behalf of the Company and Gilead as are customarily found in transactions of this nature, including representations and operative provisions as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The License Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

Equity Investment

In connection with the parties' entry into the Collaboration Agreement, on December 19, 2018, the Company agreed to sell to Gilead 980,392 shares (the "Shares") of common stock, par value $0.001 per share, of the Company (the "Common Stock"), for aggregate cash consideration of approximately $30 million (the "Equity Investment"), pursuant to the terms of a Share Purchase Agreement, dated the Effective Date, by and between the Company and Gilead (the "Share Purchase Agreement"). Gilead agreed to purchase the Shares at a price of $30.60 per share. This sale does not involve a public offering and is therefore exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). Based on 25,237,309 shares of Common Stock outstanding as of December 14, 2018, following the Equity Investment, Gilead will beneficially own approximately 3.7% of the Company's outstanding Common Stock. The Share Purchase Agreement contains customary representations, warranties, and covenants of each of the parties thereto, including certain transfer and standstill restrictions.

Registration Rights Agreement

In connection with the Share Purchase Agreement, the Company and Gilead have also entered into a Registration Rights Agreement as of the Effective Date (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement and subject to the lock-up restrictions provided in the Share Purchase Agreement, Gilead will have customary demand and piggyback registration rights. The Registration Rights Agreement will require the Company to pay certain expenses relating to such registrations, and Gilead and the Company have also agreed to indemnify each other under the registration statement from certain liabilities. The Registration Rights Agreement will become effective upon the effectiveness of the consent provided in the Irrevocable Registration Rights Waiver and Amendment as further described below.

Irrevocable Registration Rights Waiver and Amendment

Certain of the Company's existing investors party to that certain Investors' Rights Agreement (the "Existing IRA") by and among the Company and the parties thereto, dated as of December 22, 2017, are being asked to execute an Irrevocable Registration Rights Waiver and Amendment to consent to (i) the grant of certain registration rights to Gilead and (ii) the amendment to certain provisions of the Existing IRA to harmonize certain terms related to registrable securities cutbacks with those contained in the Registration Rights Agreement.

The foregoing description of the material terms of the Collaboration Agreement, License Agreement, Share Purchase Agreement, Registration Rights Agreement, and Irrevocable Registration Rights Waiver and Amendment (together, the "Agreements") is qualified in its entirety by reference to the complete texts of the Agreements, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission.

Item 3.02 Unregistered Sales of Equity Securities.

The information set forth under the heading "*Equity Investment*" in Item 1.01 is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On December 19, 2018, the Company and Gilead issued a joint press release regarding the collaboration, a copy of which is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the Company on December 19, 2018, furnished hereto.

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.

Scholar Rock Holding Corporation

Date: December 19, 2018

By: /s/ Junlin Ho
Junlin Ho
VP, Head of Corporate Legal

Exhibit 99.1

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For Confidential Review

GILEAD SCIENCES AND SCHOLAR ROCK ANNOUNCE STRATEGIC COLLABORATION TO DEVELOP NOVEL THERAPIES FOR FIBROTIC DISEASES

– Companies to Develop Highly Specific Inhibitors of Local TGFβ Activation –

Foster City, Calif., and Cambridge, Mass., December 19, 2018 – Gilead Sciences, Inc. (NASDAQ: GILD) and Scholar Rock Holding Corporation (NASDAQ: SRRK) announced today that the companies have entered into a strategic collaboration to discover and develop highly specific inhibitors of transforming growth factor beta (TGFβ) activation for the treatment of fibrotic diseases.

Under the collaboration, Gilead has exclusive options to license worldwide rights to product candidates that emerge from three Scholar Rock TGFβ programs: inhibitors that target activation of latent TGFβ1 with high affinity and specificity, inhibitors that selectively target activation of latent TGFβ1 localized to extracellular matrix, and a third TGFβ discovery program. Scholar Rock is responsible for antibody discovery and preclinical research through product candidate nomination, after which, upon exercising the option for a program, Gilead will be responsible for the program's preclinical and clinical development and commercialization. Scholar Rock retains exclusive worldwide rights to discover, develop, and commercialize certain TGFβ inhibitors for oncology and cancer immunotherapy.

"Gilead is committed to developing innovative therapies that address a range of fibrotic diseases, including non-alcoholic steatohepatitis and diabetic kidney disease," said John McHutchison, MD, AO, Chief Scientific Officer and Head of Research and Development, Gilead Sciences. "We are excited to work with Scholar Rock to investigate this novel approach to TGFβ inhibition as an important aspect of our research programs in fibrotic diseases."

In connection with the collaboration agreement, Scholar Rock will receive $80 million in upfront payments, comprised of $50 million cash and $30 million purchase of Scholar Rock Holding Corporation common stock. In addition, Scholar Rock will receive a one-time milestone payment of $25 million upon the successful completion of specific preclinical studies and be eligible to receive up to an additional $1,425 million in potential payments aggregated across all three programs based on the successful achievement of certain research, development, regulatory and commercialization milestones. Scholar Rock would also receive high single-digit to low double-digit tiered royalties on sales of potential future products originating from the collaboration.

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"Gilead's commitment to developing innovative therapies for fibrotic diseases makes the company an ideal partner to maximize the value of candidates from our TGFβ program," said Nagesh Mahanthappa, Ph.D, President and CEO of Scholar Rock. "This collaboration also emphasizes our belief in the tremendous potential of Scholar Rock's broad pipeline of highly specific modulators targeting the TGFβ superfamily, with potential applications in a wide range of serious diseases, including neuromuscular disorders, cancer, fibrosis and anemia."

Fibrosis is a debilitating pathological feature of many diseases that scars tissues and vital organs and is a major cause of morbidity and mortality. TGFβ-driven signaling is thought to be a central regulator of fibrosis. Inhibitors of TGFβ signaling discovered through Scholar Rock's proprietary platform have been shown to selectively prevent the activation of the growth factor in the fibrotic matrix in vitro and in preclinical models. By targeting the disease microenvironment, these highly specific inhibitors of TGFβ activation may offer a novel approach to suppressing pro-fibrotic signaling in multiple organs.

About Scholar Rock

Scholar Rock is a clinical-stage biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. Scholar Rock is creating a pipeline of novel product candidates with the potential to transform the lives of patients suffering from a wide range of serious diseases, including neuromuscular disorders, cancer, fibrosis and anemia. Scholar Rock's newly elucidated understanding of the molecular mechanisms of growth factor activation enabled it to develop a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target these signaling proteins at the cellular level. Scholar Rock believes its focus on biologically validated growth factors may facilitate a more efficient development path. For more information, please visit www.ScholarRock.com or follow Scholar Rock on Twitter (@ScholarRock) and LinkedIn (https://www.linkedin.com/company/scholar-rock/).

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Scholar Rock Forward-Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Scholar Rock's future expectations, plans and prospects, including without limitation, Scholar Rock's expectations regarding the potential of the TGFβ program and Scholar Rock's collaboration with Gilead. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify such forward-looking statements. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements.

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These risks and uncertainties include those risks more fully discussed in the section entitled "Risk Factors" in Scholar Rock's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, as well as discussions of potential risks, uncertainties, and other important factors in Scholar Rock's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements represent Scholar Rock's views only as of today and should not be relied upon as representing its views as of any subsequent date. All information in this press release is as of the date of the release, and Scholar Rock undertakes no duty to update this information unless required by law.

Gilead Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that the parties may not realize the potential benefits of this collaboration and Gilead may fail to develop and/or commercialize any product candidates from the TGFβ program. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.