

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 2, 2025

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

Delaware
(State or Other Jurisdiction of
Incorporation)

001-38501
(Commission File Number)

82-3750435
(I.R.S. Employer Identification Number)

301 Binney Street, 3rd Floor, Cambridge, MA 02142
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	SRRK	The Nasdaq Global Select Market

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 8.01. Other Events.

As previously disclosed, on October 10, 2025, Catalent Indiana, LLC (part of Novo Nordisk) (“Catalent Indiana”) informed Scholar Rock Holding Corporation (the “Company”) that, following the Form FDA 483 issued to Catalent Indiana, LLC on July 14, 2025, the U.S. Food and Drug Administration (the “FDA”) determined that the inspection classification of this facility is “official action indicated.” Catalent Indiana has since informed the Company that Catalent Indiana received a warning letter from the FDA (the “warning letter”). Catalent Indiana continues to work with the FDA to resolve the outstanding issues cited in the warning letter. Based on the November 12, 2025 Type A Meeting and currently available information from Catalent Indiana, the Company continues to anticipate resubmission of its biologics license application and U.S. launch of apitegromab in spinal muscular atrophy, following approval, in 2026.

Cautionary Notes on Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In this context, forward-looking statements often address expected future business and financial performance and financial condition, and often contain words such as “anticipate,” “believe,” “expect,” “intend,” “plan,” “seek,” “see,” “will,” “would,” “may,” “target,” and similar expressions and variations or negatives of these words. Forward-looking statements by their nature address matters that are, to different degrees, uncertain, such as statements regarding Catalent Indiana’s response to the FDA, the Company’s regulatory submissions and anticipated approvals, and the impact of any further action by the FDA. These and other forward-looking statements are not guarantees of future results and are subject to risks, uncertainties and assumptions that could cause actual results to differ materially from those expressed in any forward-looking statements. Important risk factors that may cause such a difference include, but are not limited to the risks described in the Company’s most recent quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2025. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof. The provision of the information in this report shall not be deemed an admission as to the materiality of any of the information contained herein.

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 2, 2025

By: /s/ Junlin Ho

Junlin Ho

General Counsel & Corporate Secretary
