

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): October 3, 2025

Rocket Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36829
(Commission File Number)

04-3475813
(IRS Employer Identification No.)

9 Cedarbrook Drive, Cranbury, NJ
(Address of principal executive offices)

08512
(Zip Code)

Registrant's telephone number, including area code: (646) 440-9100

Not applicable
(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 (see General Instruction A.2):

- 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, \$0.01 par value	RCKT	The Nasdaq Global Market

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.

Item 8.01. Other Events.

On October 3, 2025, Rocket Pharmaceuticals, Inc. (“Rocket” or the “Company”) reported that it has voluntarily withdrawn its Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) for mozafancogene autotemcel (also known as “Fansky,” “Fanca-cel,” or “RP-L102”), an investigational gene therapy for the treatment of Fanconi Anemia (“FA”).

This decision follows the Company’s previously announced corporate prioritization, under which Rocket is focusing its resources on programs with the clearest regulatory and commercial pathways. As a result, Rocket ceased new internal investment in RP-L102 in July 2025, subsequently withdrew its Marketing Authorization Application (“MAA”) with the European Medicines Agency in July 2025, and has now withdrawn its U.S. BLA.

The Company’s decision to withdraw the BLA is based on business and strategic considerations and does not reflect concerns regarding the safety or efficacy profile of RP-L102. Data generated to date continue to support that RP-L102 has been generally well tolerated, with no significant safety signals observed, and a risk-benefit profile that appears favorable.

The Company will consider external partnership opportunities that could potentially enable the advancement of RP-L102 in the future. Withdrawal of the BLA preserves Rocket’s ability to re-engage with regulators at a later date should there be an appropriate strategic or partnership pathway to sustainably progress the program

Forward-Looking Statements

Except for the factual statements made herein, information contained in this Current Report on Form 8-K consists of forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects or future events, as well as words such as “believes,” “intends,” “expects,” “plans” and similar expressions, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Such forward-looking statements are not guarantees of performance and actual actions or events could differ materially from those contained in such statements. For example, there can be no assurance that the Company will enter into any external new partnerships that enable the advancement of RP-L102. Reference is also made to other factors detailed from time to time in the Company’s periodic reports filed with the Securities and Exchange Commission, including the Company’s most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. The forward-looking statements contained in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K and the Company assumes no obligation to publicly update any forward-looking statements to reflect changes in information, events or circumstances after the date of this Current Report on Form 8-K, unless required by law.

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.

Rocket Pharmaceuticals, Inc.

Date: October 3, 2025

By: /s/ Martin Wilson

Martin Wilson

General Counsel and Chief Corporate Officer, SVP
