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): September 15, 2026

Rocket Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36829**	**04-3475813**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

9 Cedarbrook Drive, Cranbury, NJ	**08512**
(Address of principal executive offices)	(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 7.01. Regulation FD Disclosure.

On September 15, 2026, Rocket Pharmaceuticals, Inc. (the "Company") issued a press release announcing alignment with the U.S. Food and Drug Administration on continued enrollment and dosing and key elements of the global pivotal Phase 2 trial of RP-A501 for the treatment of Danon disease, including the recalibrated dose, 12-patient pivotal population and established 12-month co-primary endpoints.

A copy of the press release is included as Exhibit 99.1 hereto and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1, 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, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release of Rocket Pharmaceuticals, Inc. dated September 15, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: September 15, 2026

By: /s/ Martin Wilson
Martin Wilson
General Counsel and Chief Corporate Officer

Exhibit 99.1

Rocket Pharmaceuticals Announces FDA Alignment on Path to Complete Pivotal Phase 2 Trial of RP-A501 in Danon Disease

FDA confirms pivotal efficacy population of 12 patients, including the first three treated under the modified protocol

FDA review of initial safety data supports continued enrollment and dosing under modified protocol

FDA confirms established 12-month co-primary endpoints intended to support potential accelerated approval

Comprehensive Danon disease program webinar for October 6, 2026, at 4:30 p.m. ET

CRANBURY, N.J. – September 15, 2026 – Rocket Pharmaceuticals, Inc. (NASDAQ: RCKT), a fully integrated, commercial-stage biotechnology company advancing genetic medicines for rare and life-threatening diseases, focused on inherited cardiovascular disorders, today announced alignment with the U.S. Food and Drug Administration (FDA) on continued enrollment and dosing and key elements of the global pivotal Phase 2 trial of RP-A501 for the treatment of Danon disease, including the recalibrated dose, 12-patient pivotal population and established 12-month co-primary endpoints.

The clinical data reviewed by FDA included results from the first three patients treated under the modified protocol. All three completed at least four weeks of follow-up and had been discharged following protocol-specified observation. No clinical or laboratory evidence of thrombotic microangiopathy or capillary leak syndrome had been observed. Following its review of the available safety data, the FDA confirmed continued enrollment and dosing under the modified protocol at the recalibrated dose.

The FDA also confirmed that the pivotal study population will include 12 male patients treated with RP-A501 at the recalibrated dose of 3.8×10^{13} genome copies per kilogram (GC/kg) using commercial-grade product. Importantly, the first three patients treated at the recalibrated dose under the modified protocol count toward the 12-patient pivotal population, leaving nine additional patients to be enrolled and treated. Rocket expects to complete dosing of the remaining patients by mid-2027.

The primary assessment will occur at 12 months using the previously established co-primary endpoints of myocardial LAMP2 protein expression and a 10% reduction from baseline in left ventricular mass index. These endpoints are intended to support a potential accelerated approval pathway.

"FDA's confirmation of the pivotal efficacy framework marks an important milestone for RP-A501 and the Danon disease community," said Gaurav Shah, M.D., Chief Executive Officer of Rocket Pharmaceuticals. "With the first three patients counting toward the 12-patient pivotal population and the established co-primary endpoints preserved, we now have a clear and actionable path to complete the pivotal study. The initial clinical experience at the recalibrated dose and supportive product-bridging data further reinforce the path forward."

The modified protocol incorporates a recalibrated RP-A501 dose and an optimized immunomodulatory regimen comprised of rituximab, sirolimus and corticosteroids, together with enhanced eligibility criteria, safety monitoring and risk-mitigation measures. The recalibrated dose was selected based on analytical characterization of the Phase 2 commercial-grade product, including its full-particle content, and is supported by nonclinical bridging data.

Nonclinical bridging data further support the pharmacologic activity of the recalibrated dose. In a Danon disease mouse model, administration of Phase 2 material at 3.8×10^{13} GC/kg resulted in cardiac LAMP2B protein expression comparable to that observed at a higher dose and demonstrated comparable vector biodistribution.

Rocket plans to provide a comprehensive update on the Danon disease program during a virtual investor webinar on Tuesday, October 6, 2026, at 4:30 p.m. ET. Additional information, including webcast access details, will be available in the Investors section of the Company's website.

About Rocket Pharmaceuticals, Inc.
Rocket Pharmaceuticals, Inc. (NASDAQ: RCKT) is a fully integrated commercial-stage biotechnology company developing genetic medicines for rare and life-threatening diseases, with a strategic focus on inherited cardiovascular disorders and additional programs in hematology and immunology. Rocket's cardiovascular portfolio includes three clinical-stage gene therapy programs targeting hypertrophic, arrhythmogenic, and dilated cardiomyopathies, together representing one of the broadest pipelines focused on inherited heart disease. The Company's integrated platform combines proprietary adeno-associated virus (AAV) manufacturing capabilities, extensive clinical experience in cardiac gene therapy, and long-term safety and efficacy data supporting advancement across its cardiovascular portfolio.

For more information about Rocket, please visit www.rocketpharma.com and follow us on LinkedIn, YouTube, and X.

Rocket Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements concerning Rocket's future expectations, plans and prospects that involve risks and uncertainties, as well as assumptions that, if they do not materialize or prove incorrect, could cause results to differ materially from those expressed or implied by such forward-looking statements. Rocket makes such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical fact contained in this release are forward-looking statements.

These forward-looking statements include, but are not limited to, statements concerning the safety and potential effectiveness of RP-A501; the anticipated enrollment and dosing of additional patients in the Phase 2 trial; the expected timing for completing dosing and conducting the 12-month primary efficacy assessment; the potential for the trial's co-primary endpoints to support an accelerated approval pathway; future regulatory interactions and submissions; and the timing and content of future clinical data updates.

Although Rocket believes that the expectations reflected in these forward-looking statements are reasonable, Rocket cannot guarantee such outcomes. Actual results may differ materially as a result of various important factors, including the results of Rocket's ongoing and planned clinical trials; Rocket's ability to enroll and retain a sufficient number of patients and successfully complete clinical studies; the timing and outcome of regulatory interactions; manufacturing and product-supply considerations; unexpected safety events; and other risks more fully discussed in the section entitled "Risk Factors" in Rocket's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on February 26, 2026, and in subsequent filings with the SEC, including Rocket's Quarterly Reports on Form 10-Q.

Accordingly, readers should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and Rocket undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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