

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): June 23, 2025

**BioCryst Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-23186**  
(Commission  
File Number)

**62-1413174**  
(IRS Employer  
Identification No.)

**4505 Emperor Blvd., Suite 200**  
**Durham, North Carolina 27703**  
(Address of Principal Executive Offices) (Zip Code)

**(919) 859-1302**  
(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
<b>Common Stock</b>	<b>BCRX</b>	<b>Nasdaq Global Select Market</b>

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.

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## **Item 8.01. Other Events**

On June 23, 2025, the U.S. Food and Drug Administration (“FDA”) notified BioCryst Pharmaceuticals, Inc. (the “Company”) that it has extended the Prescription Drug User Fee Act (“PDUFA”) goal date for the Company’s new drug application (“NDA”) for the use of once-daily ORLADEYO<sup>®</sup> (berotralstat) oral granules in pediatric patients with hereditary angioedema (“HAE”) aged 2 to 11 years. The FDA determined that the Company’s submission of additional final reports and formulation data constituted a major amendment to the NDA, resulting in a standard three-month extension to the original goal date to provide time for a full review of the submission. The new PDUFA target action date is December 12, 2025.

## **Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements, including statements relating to ORLADEYO. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: the Company’s ability to successfully progress its development plans, including meeting expected timelines; ongoing and future preclinical and clinical development of product candidates may take longer than expected and may not have positive results; the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results; and the FDA or other applicable regulatory agency may not approve ORLADEYO for use in pediatric patients with HAE aged 2 to 11 years within the timeframe expected, or at all, may ultimately determine that there are deficiencies in the development program or execution thereof, may require additional information or studies, may disagree with our safety and efficacy conclusions, may impose certain restrictions, warnings, or other requirements, may impose a clinical hold, or may withhold, delay, or withdraw market approval. Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically the Company’s most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, which identify important factors that could cause the actual results to differ materially from those contained in the Company’s forward-looking statements.

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**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.

Date: June 25, 2025

**BioCryst Pharmaceuticals, Inc.**

By: /s/ Alane Barnes  
Alane Barnes  
Chief Legal Officer

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