

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): March 10, 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
Common Stock	BCRX	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 (§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.

As previously disclosed, BioCryst Pharmaceuticals, Inc. (the “Company”) received a notice letter (the “Notice Letter”) from Annora Pharma Private Limited (“Annora”) advising that Annora has submitted an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture, use or sell a generic version of ORLADEYO in the United States prior to the expiration of three patents listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”): U.S. Patent Nos. 10,662,160; 11,117,867; and 11,618,733 (the “Challenged Patents”). The Notice Letter alleges that the Challenged Patents, which expire in 2039, are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Annora’s ANDA. The Notice Letter does not challenge the following six ORLADEYO Orange Book patents that expire in 2035: U.S. Patent Nos. 10,125,102; 10,329,260; 10,689,346; 11,230,530; 11,708,333; and 12,116,346.

On March 10, 2025, the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Annora, Hetero Labs Limited, Hetero USA, Inc., and Camber Pharmaceuticals, Inc. (the “Defendants”), asserting infringement of the Challenged Patents arising from Annora’s ANDA filing with the FDA. The Company is seeking, among other remedies, equitable relief enjoining the Defendants from infringing the Challenged Patents, as well as an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of the Challenged Patents (including any regulatory extensions). The Company intends to vigorously defend its intellectual property rights protecting ORLADEYO.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the Company’s intention to vigorously defend its intellectual property rights. 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 belief 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 enforce its intellectual property rights and to defend its patents; the costs associated with the patent infringement lawsuit or any potential future lawsuits the Company may be required to file to defend its patent rights; and the possible introduction and timing of generic competition to ORLADEYO. 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.

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: March 11, 2025

BioCryst Pharmaceuticals, Inc.

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