

**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): November 5, 2019

**BioCryst Pharmaceuticals, Inc.**  
(Exact Name of Registrant as Specified in Charter)

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

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

**62-1413174**  
(I.R.S. Employer Identification Number)

**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 (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 1.01. Entry into a Material Definitive Agreement.

On November 5, 2019, BioCryst Pharmaceuticals, Inc. (“BioCryst” or the “Company”) and Torii Pharmaceutical Co., Ltd., a corporation organized under the laws of Japan (“Torii”), entered into a Commercialization and License Agreement (the “Agreement”) granting Torii the exclusive right to commercialize BCX7353, an oral, once-daily treatment for the prevention of hereditary angioedema (“HAE”) attacks, in Japan.

Under the Agreement, BioCryst will receive an upfront, non-refundable payment of \$22 million and may be eligible to receive an additional milestone payment of either \$20 million if Japan’s Pharmaceuticals and Medical Devices Agency (the “PMDA”) grants regulatory approval on or before December 31, 2020, or \$15 million if regulatory approval is granted on or before December 31, 2021. In either case, the regulatory milestone payment is contingent upon receipt of a reimbursement price approval from Japan’s National Health Insurance system in excess of the threshold specified in the Agreement.

In addition, BioCryst will be entitled under the Agreement to receive tiered royalty payments based on the amount of annual net sales of BCX7353 in Japan during each calendar year. If BCX7353 maintains its Sakigake designation during the PMDA review, the tiered royalty rate will range from twenty percent to forty percent of net sales, otherwise, the tiered royalty rate will range from fifteen percent to thirty-five percent of net sales. Torii’s royalty payment obligations are subject to customary reductions in certain circumstances, but may not be reduced by more than 50% of the amount that otherwise would have been payable to BioCryst in the applicable calendar quarter. Torii’s royalty payment obligations commence upon the first commercial sale of BCX7353 in Japan and expire upon the later of (i) the tenth anniversary of the date of first commercial sale of BCX7353 in Japan, (ii) the expiration of BioCryst’s patents covering BCX7353, and (iii) the expiration of regulatory exclusivity for BCX7353 in Japan (the “Royalty Term”). BioCryst will be responsible for supplying Torii with its required amounts of BCX7353. The activities of the parties pursuant to the Agreement will be overseen by a Joint Steering Committee, to be composed of an equal number of representatives from each party to coordinate the development and commercialization of BCX7353 in Japan.

Torii will have sole control over and decision-making authority with respect to all commercialization activities for BCX7353 for the prevention of HAE attacks in Japan, subject to oversight from a joint steering committee. On the first anniversary of the first commercial sale of BCX7353 in Japan, BioCryst will transfer and assign to Torii the ownership of and responsibility for the Japan New Drug Application (“NDA”) and all other regulatory approvals and activities related to the commercialization of BCX7353 in Japan. BioCryst retains sole decision-making authority with regard to all research and development activities with respect to BCX7353 both inside and outside of Japan, with limited exceptions to facilitate Torii’s commercialization of the product in Japan for the prevention of HAE attacks. BioCryst will remain solely responsible for all commercialization activities for BCX7353 outside of Japan.

Under the Agreement, BioCryst has granted Torii a right of first negotiation (“ROFN”) to commercialize BCX7353 in Japan for the acute treatment of HAE attacks if BioCryst develops BCX7353 for such indication. The ROFN would be triggered upon written notice from BioCryst, which must be no later than 30 days after the successful completion of a phase III clinical trial of BCX7353 for acute treatment of HAE attacks. In addition, BioCryst has granted Torii a second ROFN to commercialize any additional kallikrein inhibitor that BioCryst may develop in the future for use in HAE in Japan. Under both ROFNs, if the parties do not agree to terms with respect to a definitive amendment to the Agreement or new agreement, as applicable, the terms of the amendment or agreement would be set by a third party arbitrator.

The Agreement will remain in effect until the expiration of the Royalty Term. Either party may terminate the Agreement in its entirety if the other party breaches any of its material obligations under the Agreement, subject to applicable cure periods, or if the other party experiences a bankruptcy event. Torii may terminate the Agreement under certain limited circumstances, including the receipt of notice that certain additional development activities are required for regulatory approval BCX7353, if regulatory approval of BCX7353 is not received prior to December 31, 2022, or upon one year’s written notice after the sixth anniversary of the first commercial sale of BCX7353 in Japan. BioCryst may terminate the Agreement under certain circumstances if Torii fails to meet certain performance targets for net sales and does not remediate its failure to meet such targets. BioCryst may also terminate the Agreement under certain circumstances if Torii or any of its affiliates seek to challenge the validity of the Company’s patents or fail to conduct any material commercialization activities for a continuous period.

Upon termination of the Agreement, the licenses and rights granted by BioCryst to Torii and any sublicenses granted by Torii to third parties will terminate and all rights and regulatory approvals held by Torii relating to BCX7353 in Japan will revert to BioCryst.

### Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances 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 subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that could cause actual results to differ materially from the forward-looking statements contained herein include, without limitation, the following: the results of our partnership with Torii may not meet our current expectations (including with respect to the receipt or amounts of potential milestone or royalty payments); competitor products may limit the commercial potential of BCX7353 in Japan and the amount of any related royalties we would be entitled to receive; there are risks related to our relying on the performance of our partner, particularly with respect to the conduct of commercialization activities in line with our current expectations; there are risks related to government actions, including that decisions and other actions relating to approval, pricing, and exclusivity of BCX7353 in Japan may not be taken when expected or at all, or that the outcomes of such decisions and other actions may not be in line with our current expectations; we rely on third-party contract manufacturing organizations to manufacture BCX7353 and any failure of such parties to meet their obligations may impair our ability to supply the required amounts of BCX7353 to our partner; there are inherent risks related to commercializing drugs, including regulatory, manufacturing and supply risks; development activities for any indication may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of our HAE drug candidates (including for APeX-2, APeX-S and APeX-J) may not have positive results; we may not be able to enroll the required number of subjects in planned clinical trials; we may not advance human clinical trials as expected (including those for BCX7353); the FDA, EMA, PMDA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates (including BCX7353), or may not provide regulatory clearances, which could result in delays of planned clinical trials; and applicable regulatory bodies may impose a clinical hold with respect to, or withhold market approval for, product candidates (including BCX7353). Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and current reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in our projections and forward-looking statements.

### Item 8.01. Other Events.

On November 5, 2019, the Company issued a news release announcing the events described in Item 1.01. A copy of the news release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated November 5, 2019 entitled “BioCryst Announces Partnership with Torii Pharmaceutical to Commercialize BCX7353 in Japan for the Prevention of HAE Attacks”</a>

**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.

**BioCryst Pharmaceuticals, Inc.**

Date: November 5, 2019

By: /s/ Alane Barnes  
Alane Barnes  
Senior Vice President and Chief Legal Officer

## BioCryst Announces Partnership With Torii Pharmaceutical to Commercialize BCX7353 in Japan for the Prevention of HAE Attacks

—Agreement includes up to \$42 million of upfront and potential milestone payments plus royalties on net sales—

—JNDA submission to PMDA on track for Q1 2020—

—Deal leverages Torii's proven track record to deliver innovative therapies to Japanese patients—

RESEARCH TRIANGLE PARK, N.C., Nov. 05, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced that it has licensed commercialization rights in Japan to Torii Pharmaceutical, Co. for BCX7353, an oral, once-daily treatment for the prevention of hereditary angioedema (HAE) attacks.

BioCryst will receive a \$22 million upfront payment and is eligible to receive up to an additional \$20 million upon achievement of certain milestones. In addition, BioCryst will receive tiered royalties ranging from the mid-teens to potentially 40 percent of Japanese net sales of BCX7353.

"We are excited to partner with Torii to accelerate access for Japanese patients to BCX7353," said Jon Stonehouse, president and chief executive officer of BioCryst. "Torii has a strong and recent history of significant commercial success as a Japanese partner, and the breadth of experience and infrastructure to build the prophylactic HAE market with BCX7353."

BioCryst received Orphan Drug and Sakigake designation for BCX7353 and plans to submit a Japanese New Drug application (JNDA) to the Pharmaceuticals and Medical Devices Agency (PMDA) in the first quarter of 2020.

"Given its clinical profile and the tremendous unmet need of HAE patients here in Japan, we are honored to add BCX7353 to our portfolio," said Goichi Matsuda, president of Torii. "We are well positioned to use our experience in building disease awareness, in driving patient identification, and our broad reach across the base of treaters, including dermatologists, allergists, and other specialists, to bring this important treatment to HAE patients."

"With no approved treatments in Japan for the prevention of HAE attacks, there is a significant unmet need today," said professor Beverley Yamamoto, president of the Japanese Hereditary Angioedema Patient Association. "A safe, effective oral prophylactic therapy would offer tremendous benefit to Japanese HAE patients and their families."

### About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals discovers novel, oral small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, galidesivir, a potential treatment for Marburg virus disease and Yellow Fever, and BCX9250, an oral ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. For more information, please visit the Company's website at [www.BioCryst.com](http://www.BioCryst.com).

### About Torii Pharmaceutical Co., Ltd.

The corporate mission of Torii Pharmaceutical Co., Ltd. is to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products. Torii Pharma focuses on Renal diseases, Hemodialysis, Allergy and Skin diseases as its therapeutic areas of importance. Torii is a member of Japan Tobacco Inc. (JT) group. Collaboration with JT takes the form of functional focus, with JT undertaking R&D on new compounds and Torii integrating manufacture and marketing. In addition to Torii's independent activities, Torii's partnership with JT includes in-licensing of high-quality pharmaceuticals. More details can be found on the corporate website <https://www.torii.co.jp/en/>

### Forward-Looking Statements

This Press Release contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results, performance or achievements to be materially different from any future results, performances 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 subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that could cause actual results to differ materially from the forward-looking statements contained herein include, without limitation, the following: the results of our partnership with Torii may not meet our current expectations (including with respect to the receipt or amounts of potential milestone or royalty payments); competitor products may limit the commercial potential of BCX7353 in Japan and the amount of any related royalties we would be entitled to receive; there are risks related to our relying on the performance of our partner, particularly with respect to the conduct of commercialization activities in line with our current expectations; there are risks related to government actions, including that decisions and other actions relating to approval, pricing, and exclusivity of BCX7353 in Japan may not be taken when expected or at all, or that the outcomes of such decisions and other actions may not be in line with our current expectations; we rely on third-party contract manufacturing organizations to manufacture BCX7353 and any failure of such parties to meet their obligations may impair our ability to supply the required amounts of BCX7353 to our partner; there are inherent risks related to commercializing drugs, including regulatory, manufacturing and supply risks; development activities for any indication may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of our HAE drug candidates (including for APeX-2, APeX-S and APeX-J) may not have positive results; we may not be able to enroll the required number of subjects in planned clinical trials; we may not advance human clinical trials as expected (including those for BCX7353); the FDA, EMA, PMDA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates (including BCX7353), or may not provide regulatory clearances, which could result in delays of planned clinical trials; and applicable regulatory bodies may impose a clinical hold with respect to, or withhold market approval for, product candidates (including BCX7353). Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in our projections and forward-looking statements.

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