Pulmatrix, Inc.
Form 8-K
April 15, 2019

**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): April 15, 2019**

**PULMATRIX, INC.**

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-36199** | **46-1821392** |
|---|---|---|
| **(State of incorporation)** | **(Commission File No.)** | **(IRS Employer Identification No.)** |

**99 Hayden Avenue, Suite 390**

**Lexington, MA 02421**

**(Address of principal executive offices) (Zip Code)**

**Registrant s telephone number, including area code: (781) 357-2333**

**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. below):

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))

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 1.01 Entry Into a Material Definitive Agreement**
counsel

On April 15, 2019, Pulmatrix, Inc. (the Company ), entered into a Development and Commercialization Agreement (the Agreement ) with Cipla Technologies LLC ( Cipla ) for the co-development and commercialization, on a worldwide exclusive basis, of Pulmazole (PUR1900), the Company s inhaled iSPERSE drug delivery system enabled formulation of the antifungal drug, itraconazole, for the treatment of all pulmonary indications, including allergic bronchopulmonary aspergillosis in patients with asthma.

Pursuant to the Agreement, within 30 days following April 15, 2019, Cipla will make an initial upfront payment of $22 million to the Company (the Upfront Payment ) in exchange for an irrevocable assignment of all existing and future technologies, current and future drug master files, dossiers, third-party contracts, regulatory filings, regulatory materials and regulatory approvals, patents, and intellectual property rights, as well as any other associated rights and assets with respect to Pulmazole, specifically in relation to Pulmonary Indications ( Assigned Assets ), which Cipla will then irrevocably license back to the Company only for non-pulmonary application. In addition, Cipla will be granted a non-exclusive, perpetual, irrevocable, royalty-free and sub-licensable license with respect to the Company s iSPERSE technology, any current or future right affiliated with the Product with respect to non- pulmonary indications, and any patent or patent application that would otherwise be an Assigned Asset, but which is subject to a terminal disclaimer, in each, case for use with respect to Pulmazole for the Pulmonary Indications. As a condition precedent to signing Agreement, the Company demonstrated to Cipla that is has at least $15 million of unencumbered cash available for the development of Pulmazole. Within 30 days following the signing of the Agreement, the Company will make available at least $24 million of cash dedicated to the development of Pulmazole. After such $24 million is exhausted, each of the Company and Cipla will bear 50% of any costs incurred with respect to the development, regulatory and commercialization costs of Pulmazole. The parties will share equally the total free cash flow in relation to commercialization of Pulmazole.

The parties have agreed to create a joint steering committee (the JSC ) to have an overview of the development and commercialization activities (including all budgetary activities) in relation to the development and commercialization of Pulmazole. The JSC will be comprised of eight (8) members, with four (4) members representing Cipla and four (4) members representing the Company. The JSC will generally be responsible for approving development and commercialization plans, development budgets, and reviewing and monitoring the progress of the parties collaborative efforts under the Agreement.

Under the Agreement, the Company will be primarily responsible for the development of Pulmazole and Cipla will primarily be responsible for the commercialization of Pulmazole, in each case, in accordance with a JSC-approved plan. Each of the Company and Cipla may delegate its development or commercialization activities, as applicable, to an affiliate or other third-party consultant or subcontractor with the prior approval of the JSC, provided that such delegate complies with certain conditions. Under the Agreement, the Company will be responsible for all worldwide regulatory filings until Pulmazole shall have been approved by a regulatory authority in a certain jurisdiction. Cipla will own all regulatory filings, materials and approvals with respect to Pulmazole in relation to pulmonary indications regardless of whether such filing was made by the Company or Cipla.

Under the Agreement, the Company and Cipla have each granted the other party a right of first offer with respect to the rights and assets related to Pulmazole under the Agreement. If either party proposes to sell or in any way alienate such rights or assets, such other party will have the right, following its receipt of written notice, to purchase the rights and/or assets, as applicable, on the same terms. Cipla also has a right of first refusal with respect to any license, sale, assignment, transfer or other disposition or co-development agreement with a third party for non-pulmonary indications of Pulmazole. In addition, if either party develops Pulmazole in respect of indications other that those related to pulmonary applications or develops any other inhaled anti-fungal product, then the other party shall have a right of first offer with respect to such other indications and/or products.

The Agreement will continue in perpetuity unless terminated in accordance with its terms. The Agreement will automatically terminate upon a bankruptcy or insolvency event of the Company or Cipla. The Agreement may be terminated by a party (i) upon material breach of the other party which remains uncured for (30) days following

written notice of breach (ii) if the other party is engaged in willful misconduct or gross negligence or (iii) if the other party is engaged in fraud in connection with the negotiation, execution or performance of the Agreement (collectively, (i)-(iii), Fundamental Breaches ) by delivering written notice to the other party within 90 days after the later occurrence of the Fundamental Breach or the expiration of any cure period. If a party experiences a force majeure event that continues for 120 days, then the party experiencing such event may terminate the Agreement. In addition, either party may terminate the Agreement on country-by-country basis upon 30 days written notice under certain circumstances.

In the event of a Fundamental Breach by the Company, then Cipla shall have the right to acquire the Company s interest in Pulmazole for an amount equal to 25% of the fair market value of Pulmazole as determined by an independent third-party appraiser. If Cipla shall cause a Fundamental Breach, then the Company shall the right to acquire Cipla s interest in Pulmazole for the same amount. If the Agreement is terminated for any reason other than a Fundamental Breach, then Cipla shall continue to own absolute and exclusive ownership of Pulmazole and the intellectual property rights and other associated rights and assets with respect to Pulmazole and all licenses and sublicenses shall cease on the effective date of the termination.

The Agreement contains a mutual exclusivity obligation whereby each party agreed not to develop or commercialize another inhaled anti-fungal product containing itraconazole for pulmonary indications.

The Agreement also contains mutual indemnification obligations of the Company and Cipla.

**Item 8.01 Other Events.**

On April 15, 2019, the Company issued a press release regarding its entry into the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release, dated April 15, 2019 |

**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.

**PULMATRIX, INC.**

Date: April 15, 2019

By: /s/ William Duke, Jr.
William Duke, Jr.
Chief Financial Officer