

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

June 7, 2018

Date of Report (Date of earliest event reported)

Chimerix, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35867

(Commission File Number)

33-0903395

(IRS Employer Identification No.)

2505 Meridian Parkway, Suite 100
Durham, NC

(Address of principal executive offices)

27713

(Zip Code)

Registrant's telephone number, including area code: (919) 806-1074

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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))

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.

On June 7, 2018, in the press release attached hereto as Exhibit 99.1, Chimerix, Inc. announced that it was notified by the U.S. Food and Drug Administration that brincidofovir has been granted orphan drug designation for the treatment of patients with smallpox infection.

Forward-Looking Statements

Statements incorporated by reference into this Current Report on Form 8-K regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in our filings with the Securities and Exchange Commission, including without limitation our most recent Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements incorporated by reference into this Current Report on Form 8-K speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release of Chimerix, Inc. dated June 7, 2018.</u>

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.

Chimerix, Inc.

Dated: June 7, 2018

By: /s/ Timothy W. Trost
Timothy W. Trost
Senior Vice President, Chief Financial Officer and Corporate Secretary



Chimerix Receives Orphan Drug Designation from the FDA for Brincidofovir for the Treatment of Smallpox

DURHAM, N.C., June 7, 2018 – Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for brincidofovir for the treatment of smallpox.

Chimerix has been working with the Biomedical Advanced Research and Development Authority (BARDA) since 2011 to develop brincidofovir as a medical countermeasure for smallpox, demonstrating improved survival rates following confirmed orthopoxvirus infections in multiple animal models.

“We are very pleased to have received Orphan Drug Designation from the FDA for brincidofovir as a treatment for smallpox,” said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix. “Though declared eradicated in the late 1970s, smallpox, whether natural or synthetic, continues to be a potential global threat in today’s interconnected world. We are committed to completing the development program for brincidofovir as a much-needed treatment option for smallpox, in close collaboration with BARDA and FDA.”

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the United States. Orphan Drug Designation provides manufacturers with many benefits, including a waiver of the FDA Prescription Drug User Fee Act.

About Brincidofovir

Chimerix’s lead product candidate, brincidofovir, is a nucleotide analog that has antiviral activity against all five families of DNA viruses that affect humans, including adenoviruses and variola virus, the virus that causes smallpox. Brincidofovir has a high barrier to resistance, no myelosuppression and a low risk of nephrotoxicity. Brincidofovir has received Fast Track designation from the FDA for adenovirus, CMV and smallpox. Brincidofovir has also received Orphan Medicinal Product Designation from the European Commission for the treatment of adenovirus, for the prevention of CMV disease, and for the treatment of smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. Chimerix’s proprietary lipid conjugate technology and compound library have produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and a new clinical candidate, CMX521, the first clinical stage direct-acting antiviral for the treatment and prevention of norovirus. For further information, please visit Chimerix’s website, www.chimerix.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility that there may not be a viable continued development path for brincidofovir, that FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens, and that marketing approvals, if granted, may have significant limitations on their use. As a result, brincidofovir may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for brincidofovir with other regulatory authorities. These risks, uncertainties and other factors could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Annual Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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