CHIMERIX INC
Form 8-K
June 09, 2015

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 9, 2015

Date of Report (Date of earliest event reported)

Chimerix, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35867**	**33-0903395**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2505 Meridian Parkway, Suite 340

Durham, NC **27713**

(Address of principal executive offices) (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))

Item 8.01 Other Events.

Chimerix, Inc. (the "***Company***") is disclosing the information below for the purpose of providing an update of information previously disclosed in its other filings with the Securities and Exchange Commission.

SUPPRESS Enrollment

The Company has successfully enrolled the targeted 450 patients in its SUPPRESS trial, which is the Company's Phase 3 trial evaluating brincidofovir for the prevention of clinically significant cytomegalovirus ("***CMV***") infection in hematopoietic cell transplant ("***HCT***") recipients, also known as bone marrow or stem cell transplant recipients. The Company anticipates reporting topline data from SUPPRESS in early 2016.

Biomedical Advanced Research and Development Authority

On May 13, 2015, the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority ("***BARDA***") advised the Company that SIGA Technologies, Inc. had submitted a formal protest to the Government Accountability Office ("***GAO***") with respect to BARDA's notice of intent to use other than full and open competition to award a sole source contract to the Company for procurement of brincidofovir for the treatment of smallpox. The Company has notified the GAO of the Company's intent to intervene in the protest proceeding to protect its rights as the announced awardee under the Notice of Intent.

Research and Development Expenses

As previously announced, the Company plans to increase its research and development expenses for the foreseeable future as it continues development of brincidofovir for the prevention of CMV infection in HCT recipients, for the treatment of adenovirus infections and for the prevention of CMV in renal transplant recipients, among other research and development activities. In particular, the Company expects its research and development expenses for 2015 to significantly exceed prior year levels as a result of:

- the impact of SURPASS and SUSTAIN trial activities in 2015;
- the expansion of its AdVise trial into Europe and Australia in 2015;

- ongoing development and production of drug supply;
- commencement of various supporting studies; and
- the addition of personnel to support its Phase 3 trials, commercial drug production, and preparation of an NDA filing.

Assuming the completion and finalization of SUPPRESS, continued patient enrollment in its ongoing Phase 3 AdVise trial, the expansion of its AdVise trial into Europe, and the initiation of its SURPASS and SUSTAIN trial activities, the Company's research and development expenses for the year ending December 31, 2015 may be as high as $125.0 million. The Company is providing this forward-looking guidance with respect to 2015 research and development expenses solely in connection with the potential public offering of its common stock being announced concurrently with the filing of this Current Report on Form 8-K, and the Company does not expect to provide similar forward-looking guidance on a regular basis in the future.

Forward-Looking Statements

Statements contained in 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 the Company's filings with the Securities and Exchange Commission, including without limitation the Company's 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 contained in this Current Report on Form 8-K 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.

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 9, 2015

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