

CHIMERIX INC

FORM 8-K (Current report filing)

Filed 08/07/17 for the Period Ending 08/07/17

Address	2505 MERIDIAN PARKWAY, SUITE 100 DURHAM, NC 27713
Telephone	919.806.1074
CIK	0001117480
Symbol	CMRX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

August 7, 2017
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 2.02 Results of Operations and Financial Condition.

On August 7, 2017 , we announced our financial results for the second quarter ended June 30, 2017 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 and the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 and the attached Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d)Exhibits

Exhibit No.	Description
99.1	Press Release of Chimerix, Inc. dated August 7, 2017.

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: August 7, 2017

By: /s/ Timothy W. Trost

Timothy W. Trost

Senior Vice President, Chief Financial Officer and Corporate Secretary

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release of Chimerix, Inc. dated August 7, 2017.



Chimerix Announces Second Quarter 2017 Financial Results

- Conference Call at 8:30 a.m. ET Today -

DURHAM, N.C., August 7, 2017 -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today reported financial results and provided a corporate update for the second quarter ended June 30, 2017 .

“Throughout the second quarter, we continued to make steady progress as we advance brincidofovir for the benefit of immunocompromised patients,” said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix. “We are pleased by the enrollment in our multiple ascending dose study of IV BCV, the results of which will inform the next phase of development.”

“Our efforts in the first half of 2017 position us to achieve important milestones throughout the remainder of the year. We look forward to data from AdVance, our study of the natural history and outcomes of AdV infection in HCT recipients in Europe, including the use of off-label agents. We plan to initiate the AdAPT trial of oral brincidofovir for the treatment of adenovirus infection later this year,” continued Dr. Berrey.

Recent Highlights and Program Updates:

Initiated Multiple Ascending Dose Study of IV Brincidofovir

Chimerix commenced dosing in the multiple ascending dose (MAD) study of intravenous (IV) brincidofovir (BCV) in healthy subjects. This study is designed to evaluate the safety, tolerability and pharmacokinetics associated with multiple doses of IV BCV given once or twice weekly in healthy subjects. Data from this study will inform the continued development of this new formulation toward the planned Multi-Viral Prevention study of DNA viral infections in pediatric stem cell transplant recipients (MVP-Peds).

Additional Pipeline Updates

Study start-up activities are on-track for AdAPT, or Adenovirus after Allogeneic Pediatric Transplantation, previously referred to as Study 999. The Company is in active discussions with regulators on the final study design and intends to initiate AdAPT with short-course oral BCV later this year as previously communicated.

Development of BCV as a potential countermeasure for smallpox continues in collaboration with the Biomedical Advanced Research and Development Authority (BARDA). On Friday, Chimerix received correspondence from the FDA that indicated the Company will need to conduct a second rabbitpox study. The Company plans to seek clarification and is committed to work with the FDA and BARDA to gain agreement on next steps.

Chimerix anticipates initiation of a first-time-in-human (FTIH) study for CMX521 later this year. Identified from the Chimerix Chemical Library, CMX521 is a nucleoside analog which targets the norovirus polymerase, a part of the virus which is required for viral replication and is common to all viral strains, including genetically diverse norovirus strains that have been associated with outbreaks.

Second Quarter 2017 Financial Results

Chimerix reported a net loss of \$16.7 million , or \$0.36 per basic and diluted share, for the second quarter of 2017 . During the same period in 2016, Chimerix recorded a net loss of \$18.1 million , or \$0.39 per basic and diluted share.

Revenues for the second quarter of 2017 decreased to \$0.7 million , compared to \$1.8 million for the same period in 2016 .

Research and development expenses decreased to \$11.6 million for the second quarter of 2017 , compared to \$13.8 million for the same period in 2016 .

General and administrative expenses decreased to \$6.3 million for the second quarter of 2017 , compared to \$6.6 million for the same period in 2016 .

Loss from operations was \$17.2 million for the second quarter of 2017 , compared to a loss from operations of \$18.5 million for the same period in 2016 .

Chimerix's balance sheet at June 30, 2017 included \$251.5 million of capital available to fund operations, no debt, and approximately 47.0 million outstanding shares of common stock.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss second quarter 2017 financial results and provide a business update today at 8:30 a.m. ET. To access the live conference call, please dial 877-354-4056 (domestic) or 678-809-1043 (international) at least five minutes prior to the start time and refer to conference ID 54730100.

A live audio webcast of the call will also be available on the Investors section of Chimerix's website, www.chimerix.com . An archived webcast will be available on the Chimerix website approximately two hours after the event.

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 has produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and earlier-stage compounds. In addition, Chimerix has in early-stage development a new clinical candidate, CMX521, for the treatment and/or prevention of norovirus. For further information, please visit Chimerix's website, www.chimerix.com.

About Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has shown in vitro antiviral activity against all five families of DNA viruses that affect humans, including the herpes viruses and adenoviruses. Brincidofovir has a high barrier to resistance, no myelosuppression and 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 and for the prevention of CMV disease, and the Committee for Orphan Medicinal Products has issued a positive opinion for an Orphan Designation for the treatment of smallpox .

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, that CMX521 may not demonstrate expected activity against norovirus, 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 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 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.

CONTACT:

Investor Relations:

ir@chimerix.com

or

Will O'Connor

Stern Investor Relations

Will@sternir.com

212-362-1200

Media:

Becky Vonsiatsky

W2O Group

bvonsiatsky@w2ogroup.com

413-478-2003

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,891	\$ 51,463
Short-term investments, available-for-sale	124,637	180,558
Accounts receivable	—	1,599
Prepaid expenses and other current assets	3,148	2,845
Total current assets	<u>151,676</u>	<u>236,465</u>
Long-term investments	103,643	47,407
Property and equipment, net of accumulated depreciation	2,306	2,843
Other long-term assets	51	55
Total assets	<u>\$ 257,676</u>	<u>\$ 286,770</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,609	\$ 3,890
Accrued liabilities	6,159	6,215
Total current liabilities	<u>7,768</u>	<u>10,105</u>
Lease-related obligations	246	441
Total liabilities	<u>8,014</u>	<u>10,546</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at June 30, 2017 and December 31, 2016; no shares issued and outstanding as of June 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2017 and December 31, 2016; 47,042,762 and 46,522,475 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	47	46
Additional paid-in capital	701,329	692,422
Accumulated other comprehensive loss, net	(1,475)	(440)
Accumulated deficit	(450,239)	(415,804)
Total stockholders' equity	<u>249,662</u>	<u>276,224</u>
Total liabilities and stockholders' equity	<u>\$ 257,676</u>	<u>\$ 286,770</u>

CHIMERIX, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Contract revenue	\$ 675	\$ 1,841	\$ 1,753	\$ 3,069
Operating expenses:				
Research and development	11,636	13,759	24,378	34,695
General and administrative	6,284	6,607	12,880	13,531
Total operating expenses	17,920	20,366	37,258	48,226
Loss from operations	(17,245)	(18,525)	(35,505)	(45,157)
Interest income	565	377	1,071	749
Net loss	(16,680)	(18,148)	(34,434)	(44,408)
Other comprehensive loss:				
Unrealized (loss) gain on investments, net	(1,366)	75	(1,035)	496
Comprehensive loss	<u>\$ (18,046)</u>	<u>\$ (18,073)</u>	<u>\$ (35,469)</u>	<u>\$ (43,912)</u>
Per share information:				
Net loss, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.39)</u>	<u>\$ (0.74)</u>	<u>\$ (0.96)</u>
Weighted-average shares outstanding, basic and diluted	<u>46,863,753</u>	<u>46,214,086</u>	<u>46,719,367</u>	<u>46,199,110</u>