

CHIMERIX INC

FORM 8-K (Current report filing)

Filed 05/09/17 for the Period Ending 05/09/17

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

May 9, 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 May 9, 2017 , we announced our financial results for the first quarter ended March 31, 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 May 9, 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: May 9, 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 May 9, 2017.



Chimerix Announces First Quarter 2017 Financial Results

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

DURHAM, N.C., May 9, 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 first quarter ended March 31, 2017 .

“We have made meaningful progress advancing both the short-course oral brincidofovir program and the first of several confirmatory studies of IV brincidofovir. The single ascending dose study of IV brincidofovir (BCV) demonstrated with the first dose of 10 mg that we can achieve the plasma exposures that previously showed antiviral activity in the SUPPRESS and AdVise studies, but without the previously noted gastrointestinal (GI) limitations,” said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix. “These results together with the multiple-dose studies in healthy subjects and in infected populations will inform the planned pivotal pediatric trial for IV BCV, the MVP-Peds Study (Multi-Viral Prevention in Pediatric Allogeneic Transplant Recipients), which we hope to initiate in 2018. We look forward to advancing this important program to bring brincidofovir to immunocompromised patients suffering with these life-threatening viral infections.”

Recent Highlights and Program Updates:

Full Data from Phase 1 Dose Escalation Study of Intravenous Brincidofovir in Healthy Subjects Reported

Data from all four cohorts of the Phase 1 study of IV BCV were presented at the recent Investor Event held on April 27, 2017. In this study a total of 40 healthy subjects were randomized to receive a single dose of either IV BCV or IV placebo in one of four cohorts. IV BCV 10 mg achieved comparable plasma exposure to that achieved with the oral BCV 100 mg dose. There were no drug-related adverse events (AEs) reported in either the 10 mg or 25 mg cohorts; this dose range is likely to be selected for future studies for treatment of adenovirus and prevention of cytomegalovirus and other DNA viruses based on the antiviral activity demonstrated with oral BCV 100 mg.

Doses higher than those currently being explored for the above indications (“supratherapeutic”) of IV BCV (50 mg given over two hours in Cohort 3, 50 mg given over four hours in Cohort 4) were also administered to evaluate the potential effects of BCV on QT interval and other safety parameters. A majority of the AEs reported were mild and self-limited. Four subjects in Cohort 3 reported drug-related AEs: one drug-related GI AE, two subjects with a mild headache, and one subject reported pain and irritation at the IV infusion site. In Cohort 4, five subjects reported nine drug-related AEs: three subjects with GI AEs, two subjects with headache, and one subject with reversible elevations of liver transaminases reported as an AE.

Therapeutic doses of IV BCV were thus very well tolerated, and no new adverse events were identified with the IV formulation of BCV compared with the large safety database for oral BCV.

Clinical Development of BCV Continues

Following discussions with European regulators, Chimerix plans to initiate the AdAPT trial (Adenovirus after Allogeneic Pediatric Transplantation, previously referred to as “Study 999”) with short-course oral BCV later this year in Europe, and possibly in the US. AdAPT will recruit approximately 140 patients. Children who have received a T-cell depleted allogeneic HCT with confirmed AdV viral DNA loads greater than 1000 c/

ml in plasma within 100 days from transplant will be randomized to receive oral BCV or local standard of care which is predominantly off-label cidofovir. The study builds on the scientific understanding from multiple previous trials of BCV in patients with life-threatening AdV infection, and will provide comparative data on short-course oral BCV compared with currently available treatment. If positive, data from AdAPT could enable regulatory approval in Europe for oral BCV.

Following on the encouraging data from the single ascending dose study of IV BCV, Chimerix plans to initiate a multiple ascending dose study of IV BCV in healthy subjects, and a second study to generate multiple-dose PK and safety data in virally infected patients. These data are intended to inform the planned pivotal study of Multi-Viral Prevention of DNA viral infections in pediatric HCT recipients (MVP-Peds). Subject to the successful completion of the multiple ascending dose study, Chimerix intends to initiate the MVP-Peds study during 2018.

Development of BCV for smallpox continues in collaboration with the Biomedical Advanced Research and Development Authority (BARDA). Following completion of a planned second animal efficacy study, Chimerix plans to meet with the FDA to discuss any additional required data for a regulatory decision.

Investor Event

On April 27, 2017, Chimerix hosted an Investor Event that featured keynote presentations from Thomas Lion, MD, PhD, Professor and Medical Director of the Children's Cancer Research Institute (Vienna, Austria), who discussed the rapidly changing field of adenovirus infections in immunocompromised patients, and highlighted the need for new therapeutic options that can facilitate viral control during periods of severe immunosuppression. Dr. Lion presented research showing that adenovirus often reactivates in the gut and that early treatment can lead to significantly improved outcomes. Joshua Hill, MD, Associate in the Vaccine and Infectious Disease Division at the Fred Hutchinson Cancer Research Center (Seattle, Washington) shared his research on the frequency of multiple viral infections in both adult and pediatric transplant recipients. Dr. Hill showed that 90% of the predominately adult allogeneic HCT recipients whose samples were tested at their center had evidence of at least one DNA virus, and two-thirds had two or more DNA viruses. Of the HCT recipients who reactivated CMV, more than three-quarters had at least one other DNA virus identified and were at an increased risk of death. These data demonstrate a need for novel strategies to prevent multiple DNA viral infections and their negative impact on patient outcomes. Genovefa Papanicolaou, MD, Infectious Disease Specialist at Memorial Sloan Kettering Cancer Center (New York, NY) also spoke of her experiences with multiple DNA viruses in her allogeneic transplant recipients, which corroborated Dr. Hill's data.

First Quarter 2017 Financial Results

Chimerix reported a net loss of \$17.8 million, or \$0.38 per basic and diluted share, for the first quarter of 2017. During the same period in 2016, Chimerix recorded a net loss of \$26.3 million, or \$0.57 per basic and diluted share.

Revenues for the first quarter of 2017 decreased to \$1.1 million, compared to \$1.2 million for the same period in 2016.

Research and development expenses decreased to \$12.7 million for the first quarter of 2017, compared to \$20.9 million for the same period in 2016.

General and administrative expenses decreased to \$6.6 million for the first quarter of 2017, compared to \$6.9 million for the same period in 2016.

Loss from operations was \$18.3 million for the first quarter of 2017, compared to a loss from operations of \$26.6 million for the same period in 2016.

Chimerix's balance sheet at March 31, 2017 included \$264.7 million of capital available to fund operations, no debt, and approximately 46.7 million outstanding shares of common stock.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss first 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 3258363.

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. Chimerix recently announced 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 herpesviruses 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, 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.

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

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,866	\$ 51,463
Short-term investments, available-for-sale	139,829	180,558
Accounts receivable	811	1,599
Prepaid expenses and other current assets	2,391	2,845
Total current assets	<u>164,897</u>	<u>236,465</u>
Long-term investments	104,884	47,407
Property and equipment, net of accumulated depreciation	2,567	2,843
Other long-term assets	59	55
Total assets	<u>\$ 272,407</u>	<u>\$ 286,770</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,813	\$ 3,890
Accrued liabilities	5,819	6,215
Total current liabilities	<u>8,632</u>	<u>10,105</u>
Lease-related obligations	401	441
Total liabilities	<u>9,033</u>	<u>10,546</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at March 31, 2017 and December 31, 2016; no shares issued and outstanding as of March 31, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at March 31, 2017 and December 31, 2016; 46,651,793 and 46,522,475 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	47	46
Additional paid-in capital	696,995	692,422
Accumulated other comprehensive loss, net	(109)	(440)
Accumulated deficit	(433,559)	(415,804)
Total stockholders' equity	<u>263,374</u>	<u>276,224</u>
Total liabilities and stockholders' equity	<u>\$ 272,407</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 March 31,	
	2017	2016
Contract revenue	\$ 1,078	\$ 1,228
Operating expenses:		
Research and development	12,742	20,936
General and administrative	6,596	6,924
Total operating expenses	19,338	27,860
Loss from operations	(18,260)	(26,632)
Interest income	506	372
Net loss	(17,754)	(26,260)
Other comprehensive loss:		
Unrealized gain on investments, net	331	421
Comprehensive loss	\$ (17,423)	\$ (25,839)
Per share information:		
Net loss, basic and diluted	\$ (0.38)	\$ (0.57)
Weighted-average shares outstanding, basic and diluted	46,573,394	46,184,134