

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 8, 2016

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 340
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))

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2016, we announced our financial results for the second quarter ended June 30, 2016 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Chimerix, Inc. dated August 8, 2016.

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 8, 2016

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 8, 2016.



CHIMERIX

Chimerix Announces Second Quarter 2016 Financial Results

- European Commission Granted Orphan Drug Designation for Brincidofovir for the Treatment of Adenovirus -

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

DURHAM, N.C., August 8, 2016 -- 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, 2016.

“We believe that the results of our ongoing development program for brincidofovir have demonstrated clear clinical evidence of its potent antiviral activity against three important DNA viruses: smallpox, cytomegalovirus, and adenovirus. We are continuing to increase our understanding of brincidofovir’s antiviral potential in each of these areas and are actively pursuing trial designs that will provide a clear regulatory path forward for brincidofovir,” said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix.

“We also remain committed to understanding the potential broad spectrum efficacy of brincidofovir against other viruses, such as BK virus, and will soon be in clinical testing of a promising intravenous formulation that we believe will address the gastrointestinal side effects that affected outcomes in the Phase 3 SUPPRESS trial for prevention of CMV in hematopoietic cell transplant recipients. We are also investigating alternative formulations of brincidofovir for long-term use in the solid organ transplant setting. With the patent life for brincidofovir extending until 2034 and our strong cash position, we believe it is critical to progress these efforts while continuing to work closely with both U.S. and EU regulators.”

Program Updates:

Brincidofovir for Adenovirus

In May, Chimerix provided topline results from an interim analysis of the AdVise study that showed a strong antiviral effect, correlated with overall survival, in patients treated with brincidofovir. Results of the AdVise study demonstrated the potent antiviral activity of brincidofovir in patients with life-threatening adenovirus infection, suppressing levels in the blood to undetectable in more than 80 percent of pediatric subjects. This effect was observed even among those whose immune system had not yet rebounded following their stem cell transplant. Rapid virologic response (99 percent decline or below the limit of detection at week four) was correlated with improved survival to 24 weeks after initiation of brincidofovir in both adult and pediatric subjects with disseminated disease.

Additional 24 week data results from the AdVise study will be presented October 26-30 at IDWeek in New Orleans, LA. Chimerix has also been conducting data analyses to identify risk factors that are associated with poor outcomes and mortality.

“The AdVise study was the largest clinical study ever conducted in patients with serious adenovirus infections, and we are proud to be advancing development in the field as the first company to attempt to treat this life-threatening condition. We see firsthand the clear unmet need in this area from continued demand of approximately one patient per day for brincidofovir through our Expanded Access trial and Named Patient Program in the U.S. and EU,” said Garrett Nichols, MD, MS, Chief Medical Officer at Chimerix.

The Company also announced that it is discussing the design of an additional comparative trial in patients with serious adenovirus infection to support a potential regulatory application, with the U.S. Food and Drug Administration (FDA) and European regulators, and will provide further guidance regarding trial initiation upon completion of the trial design.

“As we look ahead to continued research of brincidofovir in adenovirus, we are pleased that the European Commission granted orphan drug designation for brincidofovir for the treatment of adenovirus,” Dr. Nichols added. Companies that obtain orphan designation benefit from a number of incentives in the European Union, including scientific advice specific for designated orphan medicines and market exclusivity for 10 years with an additional two years for medicines that have complied with an agreed pediatric investigation plan.

Investigation of New Brincidofovir Formulations

Chimerix continues to advance its intravenous (IV) formulation of brincidofovir, and expects to initiate a first-in-human study during the second half of 2016 to establish target exposure levels and safety data. Chimerix plans to apply these data to develop IV brincidofovir as a potential candidate for the prevention of cytomegalovirus (CMV) and other viruses after hematopoietic cell transplantation, and the treatment of BK virus and CMV after solid organ transplantation. Preclinical results to date have demonstrated the potential for IV brincidofovir to decrease the gastrointestinal side effects observed with orally-administered brincidofovir, when administered early after stem cell transplant.

The Company is also exploring other novel formulations to enable potential longer-term use in the solid organ transplant setting.

Brincidofovir for Smallpox

The development of brincidofovir for smallpox continues, in collaboration with the Biomedical Advanced Research and Development Authority (BARDA). Upon completion of the second animal efficacy study of brincidofovir in a smallpox model, the Company plans to meet with the FDA to discuss any additional required data for a regulatory decision for brincidofovir for the treatment of smallpox. Chimerix has provided regulators with information regarding the safety and tolerability of a short course of brincidofovir oral tablets as intended for use as a medical countermeasure in the event of a smallpox bioterror attack.

Second Quarter 2016 Financial Results

Net loss decreased to \$18.1 million, or \$0.39 per basic and diluted share, for the second quarter of 2016 compared to a net loss of \$24.8 million, or \$0.59 per basic and diluted share during the same period in 2015.

Revenues for the second quarter of 2016 decreased to \$1.8 million compared to \$4.1 million for the same period in 2015. A portion of the revenue during these periods related to reimbursable expenses associated with the Company's ongoing development contract with BARDA and in 2015 revenues also included \$1.5 million of deferred revenue related to the Company's collaboration and license agreement with ContraVir Pharmaceuticals.

Research and development expenses decreased to \$13.8 million for the second quarter of 2016, compared to \$21.9 million for the same period in 2015. This decrease was primarily due to a decrease in the Company's clinical trial expenses with the completion of the Phase 3 SUPPRESS and Advise trials and close-out of the kidney trials, partially offset by an increase in costs related to the development of the IV formulation of brincidofovir and the Expanded Access Program.

General and administrative expenses decreased to \$6.6 million for the second quarter of 2016, compared to \$7.2 million for the same period in 2015. The decrease was primarily due to a decrease in commercialization expense.

Loss from operations was \$18.5 million for the second quarter of 2016, compared to a loss from operations of \$25.0 million for the same period in 2015. The decreased loss was primarily due to lower research and development expenses, and general and administrative expenses, as previously discussed.

Chimerix's balance sheet at June 30, 2016 included \$301.5 million of capital available to fund operations, no debt, and approximately 46.2 million outstanding shares of common stock.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss its second quarter 2016 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 49760359.

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 novel antivirals in areas of high unmet medical need. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and earlier-stage clinical candidates, including CMX669. Chimerix is also advancing a clinical candidate for norovirus infection, CMX521. 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 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>June 30, 2016</u>	<u>December 31, 2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,060	\$ 20,605
Short-term investments, available-for-sale	240,755	199,729
Accounts receivable	313	2,432
Prepaid expenses and other current assets	4,761	6,071
Total current assets	<u>277,889</u>	<u>228,837</u>
Long-term investments	29,802	124,040
Property and equipment, net of accumulated depreciation	3,020	3,045
Other long-term assets	93	70
Total assets	<u>\$ 310,804</u>	<u>\$ 355,992</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,217	\$ 10,458
Accrued liabilities	6,311	9,721
Total current liabilities	<u>10,528</u>	<u>20,179</u>
Deferred rent	306	354
Total liabilities	<u>10,834</u>	<u>20,533</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued and outstanding as of June 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2016 and December 31, 2015; 46,214,895 and 46,162,525 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	46	46
Additional paid-in capital	684,015	675,591
Accumulated other comprehensive loss, net	(269)	(764)
Accumulated deficit	(383,822)	(339,414)
Total stockholders' equity	<u>299,970</u>	<u>335,459</u>
Total liabilities and stockholders' equity	<u>\$ 310,804</u>	<u>\$ 355,992</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,	
	2016	2015	2016	2015
Revenues:				
Contract revenue	\$ 1,841	\$ 2,598	\$ 3,069	\$ 3,833
Collaboration and licensing revenue	—	1,545	—	1,548
Total revenues	1,841	4,143	3,069	5,381
Operating expenses:				
Research and development	13,759	21,860	34,695	39,365
General and administrative	6,607	7,234	13,531	13,295
Total operating expenses	20,366	29,094	48,226	52,660
Loss from operations	(18,525)	(24,951)	(45,157)	(47,279)
Interest income, net	377	136	749	199
Net loss	(18,148)	(24,815)	(44,408)	(47,080)
Other comprehensive loss:				
Unrealized gain on investments, net	75	1,144	496	1,769
Comprehensive loss	\$ (18,073)	\$ (23,671)	\$ (43,912)	\$ (45,311)
Per share information:				
Net loss, basic and diluted	\$ (0.39)	\$ (0.59)	\$ (0.96)	\$ (1.13)
Weighted-average shares outstanding, basic and diluted	46,214,086	42,079,716	46,199,110	41,614,494