

CHIMERIX INC

FORM 8-K (Current report filing)

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Address	2505 MERIDIAN PARKWAY, SUITE 100 DURHAM, NC 27713
Telephone	919.806.1074
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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

March 2, 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))
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Item 2.02 Results of Operations and Financial Condition.

On March 2, 2017, we announced our financial results for the fourth quarter and full year ended December 31, 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 March 2, 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: March 2, 2017

By: /s/ Timothy W. Trost

Timothy W. Trost

Senior Vice President, Chief Financial Officer and Corporate Secretary



Chimerix Announces Fourth Quarter and Full Year 2016 Financial Results

*- Successful Administration of IV Brincidofovir 50 mg in Ongoing Dose Escalation Study -
- Demonstrates Favorable Safety and Tolerability Profile -*

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

DURHAM, N.C., March 2, 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 fourth quarter and full year ended December 31, 2016.

“Today we are pleased to report the positive outcome from the third cohort of our Single Ascending Dose study of intravenous brincidofovir, which demonstrated continued safety and tolerability at higher doses and further supports brincidofovir’s potential as a potent broad spectrum antiviral,” said Garrett Nichols, MD, MS, Chief Medical Officer of Chimerix.

“During 2016 we made considerable progress developing the optimal paths forward for oral brincidofovir for short course treatment and advancing intravenous brincidofovir into the clinic. These developments have positioned the Company well to achieve a number of milestones throughout 2017 that we believe will be instrumental in advancing brincidofovir in order to benefit patients fighting these serious viral infections,” concluded Michelle Berrey, MD, MPH, President and Chief Executive Officer.

The ability to provide brincidofovir (BCV) in oral and intravenous (IV) formulations enables development across multiple indications and populations with the potential for best-in-class efficacy and safety. In 28-day animal studies and in single dose administration in healthy subjects, IV BCV has shown the potential for less gastrointestinal (GI) injury compared to oral BCV, even with higher plasma drug concentrations and longer-term dosing . Additionally, data from animal efficacy studies and AdVise support the continued development of oral BCV for short course treatment of smallpox and adenovirus (AdV).

Recent Highlights and Program Updates:

Reported Preliminary Data from Ongoing Phase 1 Dose Escalation Study of IV BCV in Healthy Subjects

In this Phase 1 study, a total of 40 healthy subjects have been randomized to receive either a single dose of IV BCV or IV placebo in one of four cohorts:

- Cohort 1: IV BCV 10 mg (n=6) or placebo (n=2);
- Cohort 2: IV BCV 25 mg (n=6) or placebo (n=2);
- Cohort 3: IV BCV 50 mg given over 2 hours (n=9) or placebo (n=3); and
- Cohort 4: IV BCV 50 mg given over 4 hours (n=9) or placebo (n=3).

In January 2017, Chimerix announced preliminary data from the first two cohorts of this ongoing Phase 1 study. Today, Chimerix announces preliminary results from the third cohort (IV BCV 50 mg given over 2 hours) of this study.

In this ongoing blinded study, a favorable safety and tolerability profile has been observed in all three cohorts completed to date. Grade 1-2 (on a scale of Grade 1-5) safety laboratory changes were observed in some subjects in the first three dosing cohorts; none were considered clinically significant. No Grade 3 or higher safety laboratory abnormalities were observed for any subjects receiving IV study drug in Cohorts 1, 2 and 3. In Cohort 3, IV BCV 50 mg or placebo, mild Adverse Events (AEs) were reported that possibly were related to study drug included: a single lower gastrointestinal event of loose stools was reported in one subject, and two other subjects each reported a mild headache that spontaneously resolved. In addition, three subjects had bruising at the site of the IV catheter. IV BCV 50 mg provided plasma drug exposures higher than achieved with oral BCV dosing, and in the range of exposures targeted for treatment indications such as for BK nephropathy.

Cohort 4 will explore IV BCV 50 mg or placebo over a longer period of infusion. Complete clinical and pharmacokinetic data from all four cohorts are expected to be reported during the first half of 2017.

Presented Final Data from AdVise Trial at BMT Tandem Meetings

On February 23, final data from the AdVise trial of BCV for the treatment of AdV infection in allogeneic hematopoietic cell transplant (HCT) recipients was presented at the combined annual meetings of the Center for International Blood & Marrow Transplant Research (CIBMTR) and the American Society for Blood and Marrow Transplantation (ASBMT) held February 22-26, 2017 in Orlando, FL.

The AdVise trial was an open-label, multicenter study designed to evaluate the efficacy, safety and overall tolerability of oral BCV for the treatment of AdV infection. Pediatric and adult subjects were assigned to one of three cohorts:

- Cohort A – allogeneic HCT recipients with asymptomatic or limited AdV infection;
- Cohort B – allogeneic HCT recipients with disseminated AdV disease; and
- Cohort C – autologous HCT recipients, solid organ transplant recipients and other patients with serious AdV infections.

All subjects were to receive 12 weeks of oral BCV and were followed for at least 36 weeks. This final analysis includes 158 allogeneic HCT recipients assigned to Cohorts A (23 adult and 42 pediatric patients) and B (35 adult and 58 pediatric patients).

In the AdVise trial, declines in AdV viral load of $\geq 2 \log_{10}$ c/mL or below the limit of detection at week four were observed in 76 percent of pediatric patients and 45 percent of adult patients. Notably, this antiviral effect was observed even in HCT recipients who did not yet have immune recovery. In Cohort A, 55 percent of patients with baseline low immunity (CD4 counts < 50 cells/ μ L) achieved $\geq 2 \log_{10}$ c/mL decline or undetectable AdV at week four. In Cohort B, 52 percent of patients with baseline low immunity achieved $\geq 2 \log_{10}$ c/mL decline or undetectable AdV over the same period of time.

In patients with disseminated disease, rapid virologic response, defined as undetectable AdV viremia at week six, was associated with nearly double the survival rate and lower AdV-associated mortality compared with subjects who did not have an antiviral response, as summarized in the table below.

		Mortality		AdV-Associated Mortality
Pediatric	Responder*	7/28 (25%)	} p=0.031	1/28 (4%)
	Non-responder	7/13 (54%)		2/13 (15%)
Adult	Responder*	5/10 (50%)	} p=0.0004	0/10 (0%)
	Non-responder	13/14 (93%)		10/14 (71%)

* Responders defined as subjects with baseline AdV viremia still on study at week six who had undetectable plasma AdV at week six; non-responders defined as subjects who did not achieve the specified cut-off. A Cox model was used to compare mortality at 36 weeks in responders and non-responders.

Diarrhea was the most commonly reported treatment-emergent adverse event in AdVise Cohorts A and B, reported at 38 percent of adult and 43 percent of pediatric HCT recipients. Treatment discontinuations related to diarrhea in Cohorts A and B occurred in 5 percent of adult and 6 percent of pediatric patients.

Fourth Quarter 2016 Financial Results

Chimerix reported a net loss of \$15.0 million, or \$0.32 per basic and diluted share, for the fourth quarter of 2016. During the same period in 2015, Chimerix recorded a net loss of \$37.8 million, or \$0.82 per basic and diluted share.

Revenues for the fourth quarter of 2016 decreased to \$2.0 million, compared to \$3.1 million for the same period in 2015.

Research and development expenses were \$11.7 million for the fourth quarter of 2016, and \$31.8 million for the same period in 2015. General and administrative expenses decreased to \$5.6 million for the fourth quarter of 2016, compared to \$9.5 million for the same period in 2015.

Loss from operations was \$15.4 million for the fourth quarter of 2016, compared to a loss from operations of \$38.2 million for the same period in 2015.

Interest income was \$416,000 in the fourth quarter of 2016, compared to interest income of \$381,000 in the same period in 2015.

Chimerix's balance sheet as of December 31, 2016, included \$278.1 million of capital available to fund operations, no debt and approximately 46.5 million outstanding shares of common stock.

Full Year 2016 Financial Results

Chimerix reported a net loss of \$76.4 million, or \$1.65 per basic and diluted share, for the year ended December 31, 2016. For the year ended December 31, 2015, Chimerix recorded net loss of \$117.4 million, or \$2.67 per basic and diluted share.

Revenues for 2016 decreased to \$5.7 million, compared to \$10.8 million in 2015.

Research and development expenses were \$58.6 million for the year ended December 31, 2016, compared to \$97.7 million for the year ended December 31, 2015. General and administrative expenses decreased to \$25.0 million for the year ended December 31, 2016, compared to \$31.3 million for the year ended December 31, 2015.

Loss from operations was \$78.0 million for the year ended December 31, 2016, compared to a loss from operations of \$118.3 million for the year ended December 31, 2015.

Net interest income was \$1.6 million for the year ended December 31, 2016, compared to net interest income of \$0.9 million for the year ended December 31, 2015.

Today's Conference Call and Webcast

Chimerix will host a conference call and live webcast to discuss its fourth quarter and full year 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 97022450.

A live audio webcast of the call and accompanying slides 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 and developing 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.

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 brincidofovir may not continue to show positive safety and tolerability at higher doses, that Chimerix may not be able to achieve milestones in 2017 to advance the development of brincidofovir, 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-K 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)

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,463	\$ 20,605
Short-term investments, available-for-sale	180,558	199,729
Accounts receivable	1,599	2,432
Prepaid expenses and other current assets	2,845	6,071
Total current assets	<u>236,465</u>	<u>228,837</u>
Long-term investments	47,407	124,040
Property and equipment, net of accumulated depreciation	2,843	3,045
Other long-term assets	55	70
Total assets	<u>\$ 286,770</u>	<u>\$ 355,992</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,890	\$ 10,458
Accrued liabilities	6,215	9,721
Total current liabilities	<u>10,105</u>	<u>20,179</u>
Lease-related obligations	441	354
Total liabilities	<u>10,546</u>	<u>20,533</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at December 31, 2016 and 2015; no shares issued and outstanding as of December 31, 2016 and 2015	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at December 31, 2016 and 2015; 46,522,475 and 46,162,525 shares issued and outstanding at December 31, 2016 and 2015, respectively	46	46
Additional paid-in capital	692,422	675,591
Accumulated other comprehensive loss	(440)	(764)
Accumulated deficit	(415,804)	(339,414)
Total stockholders' equity	<u>276,224</u>	<u>335,459</u>
Total liabilities and stockholders' equity	<u>\$ 286,770</u>	<u>\$ 355,992</u>

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

	Three Months Ended December 31,		Years Ended December 31,	
	2016	2015	2016	2015
Revenues:				
Contract revenue	\$ 1,980	\$ 3,110	\$ 5,702	\$ 9,214
Collaboration and licensing revenue	-	-	-	1,548
Total revenues	1,980	3,110	5,702	10,762
Operating expenses:				
Research and development	11,705	31,849	58,647	97,717
General and administrative	5,648	9,484	25,007	31,296
Total operating expenses	17,353	41,333	83,654	129,013
Loss from operations	(15,373)	(38,223)	(77,952)	(118,251)
Interest Income, net	416	381	1,562	879
Net loss	(14,957)	(37,842)	(76,390)	(117,372)
Other comprehensive loss:				
Unrealized (loss) gain on investments, net	(74)	(1,120)	324	(799)
Comprehensive loss	\$ (15,031)	\$ (38,962)	\$ (76,066)	\$ (118,171)
Per share information:				
Net loss, basic and diluted	\$ (0.32)	\$ (0.82)	\$ (1.65)	\$ (2.67)
Weighted-average shares outstanding, basic and diluted	46,431,809	46,151,384	46,267,064	43,878,326