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, 2019
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 100 **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))

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CMRX	The Nasdaq Global Market

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, we announced our financial results for the first quarter ended March 31, 2019 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, 2019.

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, 2019

By: /s/ Timothy W. Trost

Timothy W. Trost

Senior Vice President, Chief Financial Officer and Corporate Secretary

CHIMERIX

Chimerix Announces First Quarter 2019 Financial Results and Strategy Update

- Reports Positive Top-line Survival Data from Pivotal Mouse Study as Key Milestone on Path to Smallpox Regulatory Submission -

- Plan to Focus on Execution of Smallpox Program, Halting All Other Brincidofovir Development Activities -

- Restructuring to Reduce Workforce by More Than 50%, Maintaining Key Capabilities and Preserving Capital for New Programs -

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

DURHAM, N.C., May 9, 2019 -- Chimerix (NASDAQ:CMRX), today reported financial results for the first quarter ended March 31, 2019 and provided an update on corporate strategy. Chimerix announced positive top-line results from the in-life portion of the mousepox study with ectromelia virus (ECTV), the Company's second animal model under the Food and Drug Administration (FDA) Animal Efficacy Rule. In addition, Chimerix announced the discontinuation of all ongoing human clinical trials for oral and intravenous brincidofovir (BCV) due to low patient accrual across all active trials. Reflecting these developments, Chimerix plans to undertake a corporate restructuring, including a greater than 50% reduction in staff. The Company intends to pursue external opportunities to build its pipeline of product candidates.

"We're very pleased to now have shown significant improvements in survival, the primary endpoint in both the rabbitpox and mousepox animal models. This is a key milestone on the path toward an anticipated 2020 New Drug Application (NDA) of oral BCV as a medical countermeasure for smallpox and the potential for associated non-dilutive capital," stated Mike Sherman, Chief Executive Officer of Chimerix. "We are committed to pursuing programs where we can quickly address unmet patient needs with a meaningful benefit. Following an objective assessment of all internal activities, we will focus resources on the execution of the smallpox program as we identify additional attractive opportunities to create value for patients and shareholders. Our decisiveness here is a reflection of our determination to create value and help patients.

The decision to reduce staff following these strategic decisions was a difficult but necessary action. We are thankful for the commitment of these talented employees who have contributed so much to the Company. We will be working closely with those affected by the restructuring to support them in this transition," added Mr. Sherman.

The Company plans to make the existing clinical supply of BCV available to patients as part of the expanded access program.

First Quarter and Recent Highlights

BCV for Smallpox

Today, Chimerix announced positive top-line results from the in-life portion of the ECTV study, which examined BCV using the Company's second animal model of human smallpox conducted under the Animal Efficacy Rule. Chimerix is collaborating with the Biomedical Advanced Research and

Development Authority (BARDA) for the development of BCV as a potential medical countermeasure for smallpox.

The study was a randomized, blinded, placebo-controlled, parallel-group study to evaluate the efficacy of two different BCV dosing regimens versus a placebo (PBO) control group in mice infected with the mousepox virus. Mice were randomized to one of the following BCV treatment groups or placebo:

- A BCV dose regimen of 20/5/5 mg/kg administered at 48-hour intervals with treatment initiation on post-infection days 4, 5, 6 or 7; or
- A BCV dose regimen of 10/5/5 mg/kg administered at 48-hour intervals with treatment initiation on post-infection days 4, 5 or 6.

	BCV Treatment Initiation Post Infection	**Overall Survival**	**P value vs PBO**
20/5/5 BCV Dose Regimen	Day 4	27 / 32 (84%)	<0.0001
	Day 5	24 / 32 (75%)	<0.0001
	Day 6	15 / 32 (47%)	0.0014
	Day 7	12 / 32 (38%)	0.012
10/5/5 BCV Dose Regimen	Day 4	25 / 32 (78%)	<0.0001
	Day 5	21 / 32 (66%)	<0.0001
	Day 6	11 / 32 (34%)	0.023
Placebo	N/A	4 / 32 (13%)	N/A

As shown above, all BCV treatment groups demonstrated a statistically significant survival benefit compared with placebo regardless of treatment initiation day. Survival was highest in both treatment groups where BCV was administered on Day 4, with the 20/5/5 mg/kg treatment regimen showing 84% survival and the 10/5/5 regimen showing 78% survival. Survival in the placebo group was 13%. The median time to death in animals receiving placebo was 8.5 days after infection, indicating that BCV treatment was effective at preventing mortality from mousepox virus even when treatment was initiated well past the midpoint of disease.

Data from this mousepox study and the Company's rabbitpox studies are intended to address the requirement under the FDA's Animal Efficacy Rule for two different animal models of efficacy. Further confirmatory analyses (e.g., secondary endpoints) of these studies are currently underway.

Contingent upon receiving final audited results of these two key animal efficacy studies, along with preparing data necessary to bridge to a recommended human dose, Chimerix intends to submit marketing applications for BCV for the treatment of smallpox in 2020.

Management and Corporate Updates

In April, Chimerix appointed Mike Sherman, former Chief Executive Officer of Endocyte, Inc., as Chief Executive Officer and Mike Andriole, former Chief Financial Officer of Endocyte, Inc., as the newly created Chief Business Officer.

As a result of the restructuring described above, the Company will incur a restructuring related charge in the second quarter of 2019.

First Quarter 2019 Financial Results

Chimerix reported a net loss of $17.7 million, or $0.35 per basic and diluted share, for the first quarter of 2019. During the same period in 2018, Chimerix recorded a net loss of $19.8 million, or $0.42 per basic and diluted share.

Revenues for the first quarter of 2019 increased to $2.4 million, compared to $0.8 million for the same period in 2018.

Research and development expenses decreased to $13.5 million for the first quarter of 2019, compared to $14.4 million for the same period in 2018.

General and administrative expenses increased to $7.7 million for the first quarter of 2019, compared to $6.7 million for the same period in 2018.

Loss from operations was $18.8 million for the first quarter of 2019, compared to a loss from operations of $20.3 million for the same period in 2018.

Chimerix's balance sheet at March 31, 2019 included $171.6 million of capital available to fund operations, no debt, and approximately 51.0 million outstanding shares of common stock. Chimerix currently expects to end 2019 with approximately $140 million in capital to fund operations which will reflect payments related to the close-out of the oral and intravenous clinical trials and severance costs from the restructuring described above.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss first quarter 2019 results and the Company's strategic 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 3891009.

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 Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has antiviral activity against all five families of DNA viruses that affect humans, including the herpesviruses, adenoviruses, and poxviruses. Brincidofovir has a high barrier to resistance, no myelosuppression and a low risk of nephrotoxicity. Brincidofovir has received Fast Track designation from the FDA and Orphan Medicinal Product Designation from the European Commission for smallpox and has Orphan Drug Designation for smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing medicines that improve outcomes for patients with life threatening diseases. Brincidofovir (BCV, CMX001) uses Chimerix's proprietary lipid conjugate. 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 and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things, Chimerix's plans to complete a restructuring and the estimated impact on cash resources, Chimerix's plans to pursue external opportunities to build its pipeline and the potential benefits of such a transaction, and the submission of marketing applications for BCV for the treatment of smallpox. Risks and uncertainties include whether the termination of oral and intravenous clinical trials of brincidofovir and the planned restructuring will have the intended impact of conserving cash resources, Chimerix's ability to identify potential external opportunities and to complete or realize a benefit from any transaction that it pursues; whether Chimerix will be able to obtain marketing approval for brincidofovir for the treatment of smallpox; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,705	$ 81,106
Short-term investments, available-for-sale	151,881	105,424
Accounts receivable	1,425	330
Prepaid expenses and other current assets	2,534	2,598
Total current assets	175,545	189,458
Property and equipment, net of accumulated depreciation	1,158	1,210
Operating lease right-of-use assets	1,232	—
Other long-term assets	53	46
Total assets	$ 177,988	$ 190,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,492	$ 4,691
Accrued liabilities	10,389	8,275
Total current liabilities	12,881	12,966
Lease-related obligations	800	144
Total liabilities	13,681	13,110
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2019 and December 31, 2018; 51,023,842 and 50,735,279 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	51	51
Additional paid-in capital	738,163	733,907
Accumulated other comprehensive gain (loss), net	48	(92)
Accumulated deficit	(573,955)	(556,262)
Total stockholders’ equity	164,307	177,604
Total liabilities and stockholders’ equity	$ 177,988	$ 190,714

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

	Three Months Ended March 31,	
	2019	**2018**
Contract revenue	$ 2,356	$ 790
Operating expenses:		
Research and development	13,515	14,359
General and administrative	7,686	6,738
Total operating expenses	21,201	21,097
Loss from operations	(18,845)	(20,307)
Other (expense) income:		
Unrealized loss on equity investment	(8)	(134)
Interest income and other, net	1,160	615
Net loss	(17,693)	(19,826)
Other comprehensive loss:		
Unrealized gain (loss) on debt investments, net	140	(103)
Comprehensive loss	$ (17,553)	$ (19,929)
Per share information:		
Net loss, basic and diluted	$ (0.35)	$ (0.42)
Weighted-average shares outstanding, basic and diluted	50,887,221	47,637,907