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 7, 2020
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))

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

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 7, 2020, we announced our financial results for the first quarter ended March 31, 2020 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 7, 2020.

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 7, 2020

By: /s/ Michael T. Andriole

Michael T. Andriole

Chief Business and Financial Officer

Chimerix Reports First Quarter 2020 Financial Results and Provides Operational Update

DSTAT Explored as a Potential Novel Treatment for the Current Pandemic While an NDA is Being Prepared for Brincidofovir to Address a Potential Future Pandemic

DURHAM, NC, May 7, 2020 -- Chimerix, Inc. (Nasdaq:CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, today reported financial results for the first quarter ended March 31, 2020 and provided an operational update.

“Responding to the COVID-19 global pandemic, we recently announced our accelerated program for dociparstat sodium (DSTAT) to combat acute lung injury (ALI) in COVID-19 patients,” stated Mike Sherman, Chief Executive Officer of Chimerix. “As we've learned more about the manifestations of COVID-19 and how it causes death in the most serious cases, it has become clear that DSTAT’s mechanisms may be uniquely positioned to address multiple aspects of the virus’ progression, including ALI and coagulative disorders that have led to a number of other conditions, including amputations, pulmonary embolisms and stroke. As a result, DSTAT has the potential to prevent the disease progression necessitating the use of mechanical ventilation, improve survival and potentially accelerate recovery.”

“Given the urgent need for effective treatments for COVID-19 related ALI, we expect to begin dosing patients in this Phase 2/3 clinical trial this month, with data from the first safety cohort from the Phase 2 portion of the study to be available in the second half of this year.

“The COVID-19 pandemic has also highlighted the importance of our global preparedness for a variety of viral outbreaks. Chimerix has been at the forefront of these measures working with the U.S. government to develop brincidofovir (BCV) for smallpox. Preparing BCV for the U.S. Strategic National Stockpile (SNS) is a critical element to protect the population from this deadly virus, whether a potential outbreak occurs naturally or through a bioterror attack. To that end, we were very pleased to receive the U.S. Food and Drug Administration’s (FDA) clearance to initiate a rolling New Drug Application (NDA) for BCV as a medical countermeasure for smallpox. We look forward to finalizing our submission mid-year and to a potential procurement contract to enable the addition of BCV to the SNS,” added Mr. Sherman.

Recent Highlights

- Received clearance from the FDA for a rolling submission of its NDA for the approval of BCV as a medical countermeasure for smallpox
- Received clearance from the FDA to initiate a Phase 2/3 Study of DSTAT in ALI patients with COVID-19
- Received clearance from the FDA to initiate a Phase 3 trial of DSTAT in Acute Myeloid Leukemia (AML) based on review of final protocol.

Expected Upcoming Milestones

- Completion of NDA submission of BCV mid-2020
- Completion of Phase 2 portion of DSTAT trial in COVID-19 in second half of 2020
- Initiation of Phase 3 trial of DSTAT in first line AML
- Potential procurement agreement for BCV prior to FDA decision on smallpox NDA

- FDA decision on BCV smallpox NDA in 2021
- Completion of manufacturing of approximately $100 million of BCV product for SNS by mid-2021.

The company previously announced a plan to initiate a Phase 3 clinical study of DSTAT for the treatment of AML in 2020 and has subsequently announced its delay due to the ongoing COVID-19 pandemic. The Company's current operational focus is on executing the DSTAT study in ALI patients with COVID-19. Next steps on the proposed AML study will be determined in the coming months.

First Quarter 2020 Financial Results

Chimerix reported a net loss of $10.4 million, or $0.17 per basic and diluted share, for the first quarter of 2020. During the same period in 2019, Chimerix recorded a net loss of $17.7 million, or $0.35 per basic and diluted share.

Revenues for the first quarter of 2020 decreased to $1.2 million, compared to $2.4 million for the same period in 2019.

Research and development expenses decreased to $8.9 million for the first quarter of 2020, compared to $13.5 million for the same period in 2019.

General and administrative expenses decreased to $3.2 million for the first quarter of 2020, compared to $7.7 million for the same period in 2019.

Loss from operations was $10.9 million for the first quarter of 2020, compared to a loss from operations of $18.8 million for the same period in 2019.

Chimerix's balance sheet at March 31, 2020 included $103.0 million of capital available to fund operations, no debt, and approximately 61.9 million outstanding shares of common stock. The Company expects to end the year with approximately $70 million in cash and cash equivalents at the end of 2020.

About Chimerix

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. Its two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

Dociparstat sodium is a potential first-in-class glycosaminoglycan compound derived from porcine heparin that has low anticoagulant activity. In vitro and in vivo animal model data support DSTAT's potential to reduce the inflammation and cellular infiltration associated with acute lung injury and address coagulation disorders associated with COVID-19 pathology (HMGB1 and PF4). Separately, DSTAT inhibits the activities of several key proteins implicated in the viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1, elastase). Randomized AML Phase 2 data suggest that DSTAT may also accelerate platelet recovery post-chemotherapy via inhibition of PF4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy. The company is conducting a randomized, double-blind, placebo-controlled, Phase 2/3 trial to determine the safety and efficacy of DSTAT in adults with severe COVID-19 who are at high risk of respiratory failure. The Phase 2 portion of the study will enroll 24 subjects to confirm the maximum safe dose and will then expand by an additional 50 patients (74 total) at the selected dose. A formal analysis of all endpoints, including supportive biomarkers will be performed at the conclusion of the Phase 2 portion of the study. Contingent upon positive results, the Phase 3 portion of the study will enroll approximately 450 subjects.

BCV is an antiviral drug candidate in development as a medical countermeasure for smallpox. For further information, please visit the Chimerix website, www.chimerix.com.

Forward-Looking Statements

This press release contains 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, the mechanism of action of DSTAT and its potential in ALI patients with COVID-19; Chimerix's ability to develop DSTAT, including the initiation of a Phase 2/3 clinical trial for DSTAT as a potential treatment for ALI associated with COVID-19; Chimerix's ability to submit and/or obtain regulatory approvals for DSTAT and BCV; and the timing and receipt of a potential procurement contract for BCV in smallpox. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that DSTAT may not achieve the endpoints of the Phase 2/3 clinical trial; risks that DSTAT or BCV may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that development activities related to DSTAT may not be completed on time or at all; risks that Chimerix may not receive a procurement contract for BCV for smallpox in a timely manner or at all; Chimerix's reliance on a sole source third-party manufacturer for drug supply; risks that ongoing or future trials may not be successful or replicate previous trial results, or may not be predictive of real-world results or of results in subsequent trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for our drugs; risks that our drugs may be precluded from commercialization by the proprietary rights of third parties; 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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,553	$ 16,901
Short-term investments, available-for-sale	78,469	96,574
Accounts receivable	1,079	1,233
Prepaid expenses and other current assets	2,639	3,385
Total current assets	106,740	118,093
Property and equipment, net of accumulated depreciation	435	540
Operating lease right-of-use assets	578	709
Other long-term assets	16	34
Total assets	$ 107,769	$ 119,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,124	$ 2,398
Accrued liabilities	5,556	6,830
Total current liabilities	6,680	9,228
Lease-related obligations	48	196
Total liabilities	6,728	9,424
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2020 and December 31, 2019; no shares issued and outstanding as of March 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2020 and December 31, 2019; 61,930,339 and 61,590,013 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	62	62
Additional paid-in capital	780,248	778,693
Accumulated other comprehensive (loss) gain, net	(11)	35
Accumulated deficit	(679,258)	(668,838)
Total stockholders’ equity	101,041	109,952
Total liabilities and stockholders’ equity	$ 107,769	$ 119,376

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

	Three Months Ended March 31,	
	2020	**2019**
Revenues:		
Contract revenue	$ 1,171	$ 2,356
Licensing revenue	70	—
Total revenues	1241	2356
Operating expenses:		
Research and development	8,949	13,515
General and administrative	3,205	7,686
Total operating expenses	12,154	21,201
Loss from operations	(10,913)	(18,845)
Other income:		
Interest income and other, net	493	1,152
Net loss	(10,420)	(17,693)
Other comprehensive loss:		
Unrealized (loss) gain on debt investments, net	(46)	140
Comprehensive loss	$ (10,466)	$ (17,553)
Per share information:		
Net loss, basic and diluted	$ (0.17)	$ (0.35)
Weighted-average shares outstanding, basic and diluted	61,742,035	50,887,221