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 5, 2021
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 August 5, 2021, we announced our financial results for the second quarter ended June 30, 2021 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 August 5, 2021.

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 5, 2021

By: /s/ Michael T. Andriole
Michael T. Andriole
Chief Business and Financial Officer

Chimerix Reports Second Quarter 2021 Financial Results and Provides Operational Update

– Received U.S. Food and Drug Administration (FDA) Approval for TEMBEXA® (brincidofovir) for the Treatment of Smallpox –

– Blinded Independent Central Review (BICR) of ONC201 Registration Cohort in Recurrent H3 K27M-mutant Glioma Expected in Fourth Quarter 2021 –

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

DURHAM, NC, August 5, 2021 -- Chimerix (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 second quarter ended June 30, 2021 and provided an operational update.

“We made considerable progress throughout the first half of 2021, highlighted by the acquisition of Oncoceutics, the initiation of the Phase 3 DASH AML trial, and the FDA approval of TEMBEXA as a medical countermeasure for smallpox. This approval is an important milestone as it marks Chimerix’s first FDA approved drug and is the first smallpox antiviral approved for all age groups, including infants, with an available oral solution for patients who have difficulty swallowing,” said Mike Sherman, Chief Executive Officer of Chimerix. “Looking ahead to the balance of the year, we expect to report the efficacy analysis by BICR for ONC201 and complete TEMBEXA manufacturing to support U.S. national preparedness.”

Recent Highlights

TEMBEXA for Smallpox

In June, the FDA granted TEMBEXA tablets and oral suspension approval for the treatment of smallpox. TEMBEXA is approved for adult and pediatric patients and is the first and only smallpox therapy approved for neonates. The oral suspension formulation is particularly important for patients who have difficulty swallowing due to age or medical status.

TEMBEXA potentially fills an important role as a treatment countermeasure to smallpox; it has a differentiated mechanism of action, a relatively high barrier to resistance and available evidence suggests it can be used in patients who have received the other approved smallpox antiviral treatment. By year-end, Chimerix expects to complete initial TEMBEXA drug product manufacturing in order to satisfy a potential procurement contract to support national preparedness in the United States.

Imipridones and ONC201

Chimerix’s acquisition of Oncoceutics, Inc., expands the Company’s oncology franchise with a late-stage, novel class of small molecule anti-cancer compounds. Oncoceutics’ lead product candidate, ONC201, has been shown in clinical testing to selectively induce tumor cell death in multiple cancer types.

The BICR of radiographic imaging will enable clinical efficacy analyses of the first 50 patients with recurrent H3-K27M-mutant diffuse midline glioma who received single agent ONC201. These analyses will include overall response rate and key supportive endpoints, such as durability of response and other

measures of clinical benefit. If favorable, these data may form the basis for an NDA submission seeking accelerated approval of ONC201 in the United States.

In addition, a Phase 1 clinical trial for ONC206, our second imipridone product candidate, and IND-enabling work for our third imipridone candidate, ONC212, remain ongoing.

DSTAT for AML

Chimerix continues enrollment in the Phase 3 **D**ociparstat in **A**ML with **S**tandard C**h**emotherapy (DASH AML) study of DSTAT for the treatment of AML. The multicenter, randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of DSTAT in combination with standard intensive induction and consolidation chemotherapy for the treatment of newly-diagnosed AML patients. Chimerix expects to unblind data following enrollment of the first 80 evaluable patients in this study to assess complete response rates and minimal residual disease rates between the study arm and the control arm. This analysis is expected to take place in the second half of 2022.

Expected 2021 Milestones

- Negotiation of a smallpox procurement agreement for TEMBEXA
- Completion of TEMBEXA drug product manufacturing to support potential shipments up to $100 million for U.S. national preparedness
- Efficacy analysis by blinded independent central review of 50-subject registration cohort of ONC201 in recurrent H3 K27M-mutant glioma.

Second Quarter 2021 Financial Results

Chimerix reported a net loss of $17.8 million, or $0.21 per basic and diluted share, for the second quarter of 2021. During the same period in 2020, Chimerix recorded a net loss of $10.0 million, or $0.16 per basic and diluted share.

Revenues for the second quarter of 2021 decreased to $0.4 million, compared to $1.4 million for the same period in 2020.

Research and development expenses increased to $13.8 million for the second quarter of 2021, compared to $8.6 million for the same period in 2020.

General and administrative expenses increased to $4.4 million for the second quarter of 2021, compared to $3.1 million for the same period in 2020.

Chimerix's balance sheet at June 30, 2021 included approximately $140 million of capital available to fund operations, $14.0 million in a note payable related to the Oncoceutics transaction, and approximately 86.2 million outstanding shares of common stock.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss second quarter 2021 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 6658827.

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 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. In June 2021, the U.S. Food and Drug Administration granted approval of TEMBEXA for the treatment of smallpox as a medical countermeasure. The Company has two other advanced clinical-stage development programs, ONC201 and dociparstat sodium (DSTAT). ONC201 is currently in a registrational clinical program for recurrent H3 K27M-mutant glioma and an efficacy analysis by blinded independent central review is expected later in 2021. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia.

About TEMBEXA

TEMBEXA is an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks. TEMBEXA is indicated for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates. TEMBEXA is not indicated for the treatment of diseases other than human smallpox disease. The effectiveness of TEMBEXA for the treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible and inducing smallpox disease in humans to study the drug's efficacy is not ethical. TEMBEXA efficacy may be reduced in immunocompromised patients based on studies in immune deficient animals.

TEMBEXA (brincidofovir) is a nucleotide analog lipid-conjugate designed to mimic a natural monoacyl phospholipid to achieve effective intracellular concentrations of the active antiviral metabolite, cidofovir diphosphate. Cidofovir diphosphate exerts its orthopoxvirus antiviral effects by acting as an alternate substrate inhibitor for viral DNA synthesis mediated by viral DNA polymerase.

IMPORTANT SAFETY INFORMATION Including BOXED WARNING

WARNING: INCREASED RISK FOR MORTALITY WHEN USED FOR LONGER DURATION

An increased incidence of mortality was seen in TEMBEXA-treated subjects compared to placebo-treated subjects in a 24-week clinical trial when TEMBEXA was evaluated in another disease.

WARNINGS AND PRECAUTIONS

Elevations in Hepatic Transaminases and Bilirubin: May cause increases in serum transaminases (ALT or AST) and serum bilirubin. Monitor liver laboratory parameters before and during treatment.

Diarrhea and Other Gastrointestinal Adverse Events: Diarrhea and additional gastrointestinal adverse events including nausea, vomiting, and abdominal pain may occur. Monitor patients, provide supportive care, and if necessary, do not give the second and final dose of TEMBEXA.
Coadministration with Related Products: TEMBEXA should not be co-administered with intravenous cidofovir.

Carcinogenicity: TEMBEXA is considered a potential human carcinogen. Do not crush or divide TEMBEXA tablets and avoid direct contact with broken or crushed tablets or oral suspension.

Male Infertility: Based on testicular toxicity in animal studies, TEMBEXA may irreversibly impair fertility in individuals of reproductive potential.

ADVERSE REACTIONS

Common adverse reactions (adverse events assessed as causally related by the investigator in ≥ 2% of subjects) experienced in the first 2 weeks of dosing with TEMBEXA were diarrhea, nausea, vomiting and abdominal pain.

USE IN SPECIFIC POPULATIONS

Pregnancy

Based on findings from animal reproduction studies, TEMBEXA may cause fetal harm when administered to pregnant individuals. Pregnancy testing should be performed before initiation of TEMBEXA in individuals of childbearing potential to inform risk. An alternative therapy should be used to treat smallpox during pregnancy, if feasible.

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 status of Chimerix's oncology programs, and the potential benefits and government procurement of TEMBEXA. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that the current clinical study data for ONC201 will not support accelerated, or any, regulatory approval; the anticipated benefits of the acquisition of Oncoceutics may not be realized; the ability to generate positive results in a Phase 3 study in acute myeloid leukemia and subsequent approval for DSTAT; risks that Chimerix will not obtain a procurement contract for TEMBEXA in 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,445	$ 46,989
Short-term investments, available-for-sale	106,584	31,973
Accounts receivable	36	340
Prepaid expenses and other current assets	4,185	2,356
Total current assets	136,250	81,658
Long-term investments	7,535	—
Property and equipment, net of accumulated depreciation	298	214
Operating lease right-of-use assets	2,612	2,825
Other long-term assets	30	26
Total assets	$ 146,725	$ 84,723
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,457	$ 1,283
Accrued liabilities	9,465	7,250
Note payable	14,000	—
Total current liabilities	24,922	8,533
Lease-related obligations	2,654	2,814
Total liabilities	27,576	11,347
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 86,249,744 and 62,816,039 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	86	63
Additional paid-in capital	946,612	785,673
Accumulated other comprehensive loss, net	(11)	—
Accumulated deficit	(827,538)	(712,360)
Total stockholders’ equity	119,149	73,376
Total liabilities and stockholders’ equity	$ 146,725	$ 84,723

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,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Contract and grant revenue	$ 390	$ 1,396	$ 1,823	$ 2,567
Licensing revenue	1	6	3	76
Total revenues	391	1,402	1,826	2,643
Operating expenses:				
Research and development	13,798	8,578	25,660	17,527
General and administrative	4,408	3,110	8,544	6,315
Acquired in-process research and development	—	—	82,890	—
Total operating expenses	18,206	11,688	117,094	23,842
Loss from operations	(17,815)	(10,286)	(115,268)	(21,199)
Other income:				
Interest income and other, net	52	270	90	763
Net loss	(17,763)	(10,016)	(115,178)	(20,436)
Other comprehensive loss:				
Unrealized gain (loss) on debt investments, net	32	141	(11)	95
Comprehensive loss	$ (17,731)	$ (9,875)	$ (115,189)	$ (20,341)
Per share information:				
Net loss, basic and diluted	$ (0.21)	$ (0.16)	$ (1.38)	$ (0.33)
Weighted-average shares outstanding, basic and diluted	86,225,836	62,042,778	83,231,600	61,892,407