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, 2022
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 8, 2022, we announced our financial results for the six months ended June 30, 2022 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 8, 2022.

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, 2022

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

Chimerix Reports Second Quarter 2022 Financial Results and Provides Operational Update

– ONC201 Phase 3 ACTION Study Planned to Initiate This Year –

–~$32M in Revenue from International TEMBEXA Agreements Recently Recognized –

– U.S. Anti-Trust Clearance Obtained for Sale of TEMBEXA to Emergent BioSolutions –

– Conference Call at 4:30 p.m. ET Today –

DURHAM, NC, August 8, 2022 -- Chimerix (Nasdaq:CMRX), a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases, today reported financial results for the second quarter ended June 30, 2022 and provided an operational update.

“We are pleased to announce the design of Phase 3 study of ONC201 for the treatment of H3 K27M mutant glioma (the ACTION study), following feedback from the U.S. Food and Drug Administration (FDA),” said Mike Sherman, Chief Executive Officer of Chimerix. “H3 K27M-mutant glioma is an invariably lethal form of brain cancer and is associated with a dismal survival expectation, making this mutation one of the worst prognoses among brain tumors. Patients desperately need new treatment alternatives. We believe this is the most advanced clinical program in development targeting this mutation and we are working with urgency to make this study available to patients. Our optimism for a successful outcome in this study is based on the characteristics of the Phase 2 data which, collectively, are differentiated from other drugs which have been evaluated in Phase 3 in the broader glioblastoma population. These characteristics include: selection of patients with a genetically specified mutation, isolation of single agent activity, observed durable responses using RANO criteria, absence of anti-angiogenic drugs which can confound imaging to yield false response or progression assessments, and consistency across multiple clinically meaningful endpoints.”

“The study will evaluate the weekly dose of ONC201 used across many clinical studies where durable tumor response has been observed in the relapsed setting. In addition, a twice per week dosing schedule will also be evaluated. This capitalizes on the safety profile of this agent and has the potential to bolster efficacy. The design positions the study to have multiple ways to achieve success,” said Dr. Timothy Cloughesy, M.D., Professor of Neurology and Molecular and Medical Pharmacology at the University of California, Los Angeles and Global Principal Investigator for the ACTION study.

“Our center is excited to participate in the upcoming ACTION Study. We expect several factors to favorably impact enrollment, including the combined RANO-HGG/LGG response rate of 30% observed after treatment with ONC201 in the relapse setting, the durability of those responses, the 2:1 ratio of patients to receive ONC201, and the sequencing of treatment to begin shortly after completion of radiation,” said Dr. Isabel Arrillaga-Romany, MD, PhD, Director of Neuro-Oncology Clinical Trials, Massachusetts General Hospital Cancer Center.

Program Updates

Phase 3 ACTION Study of ONC201 for Treatment of H3 K27M-mutant Glioma

The ACTION study is a randomized, double-blind, placebo-controlled, multicenter international study in newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation. Treatment with ONC201 will occur shortly after completion of radiation therapy. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Activation of sites is expected to begin by year-end and continue into the first half of next year.

Participants will be randomized to receive 625mg of ONC201 once per week, 625mg twice per week on two consecutive days or placebo. The dose will be scaled by body weight for pediatric patients.

The primary endpoint of the study is overall survival (OS). The study will also evaluate progression free survival (PFS) with alpha control for both OS and PFS endpoints. OS will be assessed for efficacy at three alpha-allocated timepoints: two interim assessments by the Independent Data Monitoring Committee (IDMC) at 164 events and 246 events, respectively, and a final assessment at 327 events. The final PFS analysis will be performed after 286 events, with progression assessed using RANO HGG criteria by blinded independent central review (BICR). Secondary endpoints include corticosteroid response, performance status response, change from baseline in quality of life (QoL) assessments and change from baseline in neurologic function as assessed by the Neurologic Assessment in Neuro-Oncology (NANO) scale.

Participants in the study must have a Karnofsky or Lansky performance status, a measure of patients' ability to perform ordinary tasks, of ≥70 at time of randomization. Key exclusion criteria are the presence of a primary spinal tumor, diffuse intrinsic pontine glioma, evidence of leptomeningeal spread of disease or cerebrospinal fluid dissemination.

Stratification factors include age (<21 years, ≥21 years), and an assessment of risk factors including tumor location, tumor size, and number of tumors.

The study will take place at up to 120 sites in North America, Europe and Asia Pacific. The first interim analysis is anticipated in early 2025 with final data in 2026. The study has >80% power with an assumed hazard ratio of 0.65 for OS and 0.60 for PFS. Independent comparisons will be performed for each ONC201 group versus control at each timepoint.

TEMBEXA

In June, Chimerix announced two international procurement contracts for TEMBEXA (brincidofovir), including a $25.3 million agreement with the Public Health Agency of Canada (PHAC) and a $9.3 million procurement agreement with a third party outside of North America. The majority of the volume to satisfy these orders was delivered in July 2022 resulting in approximately $32.0 million of revenue recognized during that period.

In May, Chimerix entered into an agreement with Emergent BioSolutions (EBS) for the sale of worldwide rights to TEMBEXA for $225 million upfront, potential additional milestones of up to $112.5 million and additional double digit royalties on gross profit internationally and on gross profit associated with volumes greater than 1.7 million treatment courses in the U.S. (the "Transaction").

On July 29, 2022, the waiting period expired under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR) in connection with the Transaction. This satisfies the closing condition related to the U.S. antitrust clearance of the Transaction. The Transaction remains subject to satisfaction of other closing conditions including the execution of the U.S. Biomedical Advanced Research and Development Authority (BARDA) procurement contract and the approval of the pre-novation agreement between Chimerix and EBS by BARDA.

Negotiations with BARDA for the procurement of TEMBEXA into the Strategic National Stockpile are now in the final stages.

Other Programs

The Chimerix pipeline includes development of ONC206, ONC212 and CMX521. These programs are being developed in collaboration with various institutions and universities to leverage external capital in bringing each program to its next inflection point.

ONC206 is a second generation imipridone where pre-clinical models indicate potentially improved, anti-cancer activity relative to ONC201. ONC206 is currently being evaluated in Phase I dose escalation trials in partnership with the National Institutes of Health (NIH) and with the Pacific Pediatric Neuro-Oncology Consortium (PNOC). ONC206 is being considered for development in solid tumors, including potentially adrenal tumors, endometrial cancer and central nervous system (CNS) tumors.

ONC212, which targets GPR132 and ClpP, is in ongoing IND-enabling toxicology studies which are expected to be completed in Q4 2022 with a decision to enter clinical studies expected in 1H 2023. ONC212 is being explored pre-clinically in hematological malignancies, including AML, in partnership with MD Anderson Cancer Center and in solid tumors, including pancreatic cancer, in partnership with Brown University. A $3.4 million grant awarded to Brown University supports completion of IND-enabling studies and a potential first-in-human clinical trial.

Development of CMX521 remains ongoing as a potential prophylactic and treatment of SARS-CoV-2 (COVID-19) infection in collaboration with the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC). The pre-clinical collaboration is currently focused on determining the potential for CMX521 to be delivered orally (vs inhaled) to the pulmonary system.

Second Quarter 2022 Financial Results

Chimerix reported a net loss of $23.5 million, or $0.27 per basic and diluted share, for the second quarter of 2022. During the same period in 2021, Chimerix recorded a net loss of $17.8 million, or $0.21 per basic and diluted share.

Revenues for the second quarter of 2022 and 2021 were $0.4 million. Revenue related to the previously mentioned TEMBEXA contracts will be recognized in the third quarter.

Research and development expenses increased to $18.0 million for the second quarter of 2022, compared to $13.8 million for the same period in 2021 driven primarily by higher investments in ONC201 compared to the same period last year.

General and administrative expenses increased to $5.8 million for the second quarter of 2022, compared to $4.4 million for the same period in 2021.

Loss from operations was $23.4 million for the second quarter of 2022, compared to a loss from operations of $17.8 million for the same period in 2021.

Chimerix’s balance sheet at June 30, 2022 included $42.8 million of capital available to fund operations and approximately 87.4 million outstanding shares of common stock. The proforma cash balance at June 30, 2022, inclusive of the revenue recognized to date from the two international TEMBEXA revenue contracts, is approximately $70 million. An additional $225 million, subject to adjustment for final terms of the agreement with BARDA, is due at the expected closing of the sale of TEMBEXA to EBS. The proceeds from these transactions are expected to provide Chimerix with substantial financial strength to execute the ACTION study as well as advance our broader pipeline.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss second quarter 2022 financial results and provide a business update today at 4:30 p.m. ET. To access the live conference call, please dial 646-307-1963 (domestic) or 800-715-9871 (international) at least five minutes prior to the start time and refer to conference ID 1222397.

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 with a mission to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. The Company's most advanced clinical-stage development program, ONC201, is in development for H3 K27M-mutant glioma.

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, consummation of the Transaction, including, as a result of failing to satisfy the closing conditions to the Transaction; the satisfaction of any closing conditions in a timely manner or at all, including, without limitation; the execution of a procurement contract for TEMBEXA; the timing of the initiation of the Phase 3 clinical development of ONC201; and Chimerix's financial strength. 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 Transaction will not be completed as planned; Chimerix will not obtain a procurement contract for TEMBEXA in a timely manner, on favorable terms, or at all; risks that the initial delivery or any subsequent deliveries of TEMBEXA will not occur as planned, or at all; the anticipated benefits of the acquisition of Oncoceutics may not be realized; risks that 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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,086	$ 15,397
Short-term investments, available-for-sale	14,705	72,970
Inventories	4,126	2,760
Prepaid expenses and other current assets	3,853	4,678
Total current assets	50,770	95,805
Long-term investments	—	2,022
Property and equipment, net of accumulated depreciation	205	253
Operating lease right-of-use assets	2,189	2,404
Other long-term assets	399	56
Total assets	$ 53,563	$ 100,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,743	$ 2,788
Accrued liabilities	16,682	12,933
Deferred revenue	4,846	175
Note payable	—	14,000
Total current liabilities	23,271	29,896
Loan fees	250	—
Lease-related obligations	2,114	2,392
Total liabilities	25,635	32,288
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2022 and December 31, 2021; no shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 87,436,180 and 86,884,266 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	87	87
Additional paid-in capital	961,740	953,782
Accumulated other comprehensive loss, net	(68)	(21)
Accumulated deficit	(933,831)	(885,596)
Total stockholders’ equity	27,928	68,252
Total liabilities and stockholders’ equity	$ 53,563	$ 100,540

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,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Contract and grant revenue	$ —	$ 390	$ —	$ 1,823
Licensing revenue	440	1	455	3
Total revenues	440	391	455	1,826
Cost of goods sold	—	—	114	—
Gross Profit	440	391	341	1,826
Operating expenses:				
Research and development	18,047	13,798	37,087	25,660
General and administrative	5,840	4,408	11,472	8,544
Acquired in-process research and development	—	—	—	82,890
Total operating expenses	23,887	18,206	48,559	117,094
Loss from operations	(23,447)	(17,815)	(48,218)	(115,268)
Other (loss) income:				
Interest income and other, net	(21)	52	(17)	90
Net loss	(23,468)	(17,763)	(48,235)	(115,178)
Other comprehensive loss:				
Unrealized gain (loss) on debt investments, net	5	32	(47)	(11)
Comprehensive loss	$ (23,463)	$ (17,731)	$ (48,282)	$ (115,189)
Per share information:				
Net loss, basic and diluted	$ (0.27)	$ (0.21)	$ (0.55)	$ (1.38)
Weighted-average shares outstanding, basic and diluted	87,436,180	86,225,836	87,263,452	83,231,600