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

November 4, 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 November 4, 2021, we announced our financial results for the three and nine months ended September 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 7.01 Regulation FD Disclosure.

On November 4, 2021, we issued a press release announcing initial efficacy data from our clinical trials of ONC201 for the treatment of recurrent H3 K27M-mutant glioma. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

The information in this Item 7.01 and the attached Exhibit 99.2 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 7.01 and the attached Exhibit 99.2 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 November 4, 2021.
99.2	Press Release of Chimerix, Inc. dated November 4, 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: November 4, 2021

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

Chimerix Reports Third Quarter 2021 Financial Results and Provides Operational Update

– Announced Positive Topline Results from ONC201 in Recurrent H3 K27M-mutant Glioma –

– U.S. Food and Drug Administration (FDA) Published Article Summarizing Benefit-Risk Assessment of TEMBEXA for the Treatment of Smallpox –

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

DURHAM, NC, November 4, 2021 -- 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 third quarter ended September 30, 2021 and provided an operational update.

“We are pleased with the progress we have made in 2021 towards advancing our pipeline and validating our imipridone programs. Today, we announced positive topline results from the BICR of the ONC201 50 patient cohort in recurrent H3 K27M-mutant glioma, furthering our conviction that this program has the potential to significantly improve the standard of care for these patients with severe unmet medical need,” said Mike Sherman, Chief Executive Officer of Chimerix. “As we look to the balance of the year, we plan to continue to advance our clinical programs and expect to complete TEMBEXA® manufacturing for initial potential stockpiling in support of U.S. national preparedness.”

Recent Highlights

ONC201 for Recurrent H3 K27M-mutant Glioma

Earlier today, Chimerix reported topline data from the 50 patient cohort of ONC201 for the treatment of recurrent H3 K27M-mutant glioma. ONC201 is an orally administered small molecule dopamine receptor D2 (DRD2) antagonist and caseinolytic protease (ClpP) agonist for the treatment of recurrent gliomas that harbor the H3 K27M mutation.

According to a blinded independent central review (BICR) of the registration cohort, the overall response rate (ORR) was 20.0% (95% confidence interval (CI):10.0-33.7%) as determined by Response Assessment in Neuro-Oncology Criteria for High Grade Gliomas (RANO-HGG). The median duration of response was 11.2 months (95% CI: 3.8 – not reached) and the median time to response was 8.3 months. Prior review of ONC201 identified the most commonly reported adverse events as nausea/vomiting, fatigue and decreased lymphocyte counts. Additional supportive data, including measures of other forms of clinical benefit and survival analysis will be presented at the Society for Neuro-Oncology (SNO) Annual Meeting November 19-21, 2021.

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 FDA approved smallpox antiviral treatment. In September, an article was published in the peer review journal, *Antiviral Research*, providing a thorough assessment of TEMBEXA as a medical counter measure for smallpox. The article can be accessed at https://pubmed.ncbi.nlm.nih.gov/34582915/.

By year-end, Chimerix expects to complete initial TEMBEXA drug product manufacturing in order to execute first shipments to the strategic national stockpile in response to a potential procurement contract to support national preparedness in the United States.

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 is being conducted to 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. To date, enrollment of this study has proceeded more slowly than expected due to hospital staffing shortages related to COVID-19. We expect to complete enrollment of the first 80 evaluable patients in the second half of 2022.

Third Quarter 2021 Financial Results

Chimerix reported a net loss of $18.6 million, or $0.21 per basic and diluted share, for the third quarter of 2021. During the same period in 2020, Chimerix recorded a net loss of $11.4 million, or $0.18 per basic and diluted share.

Revenues for the third quarter of 2021 decreased to $0.1 million, compared to $1.6 million for the same period in 2020.

Research and development expenses increased to $13.8 million for the third quarter of 2021, compared to $10.0 million for the same period in 2020 driven primarily by the expanded pipeline associated with the acquisition of Oncoceutics, Inc. in January 2021.

General and administrative expenses increased to $4.9 million for the third quarter of 2021, compared to $3.2 million for the same period in 2020.

Chimerix's balance sheet as of September 30, 2021 included approximately $125 million of capital available to fund operations, $14.0 million in a note payable related to the Oncoceutics transaction, and approximately 86.8 million outstanding shares of common stock.

In accordance with the terms of the merger agreement between Chimerix and Oncoceutics, Inc., the achievement of the 20% ORR via BICR will result in a success milestone payment of $20 million to the former Oncoceutics, Inc. shareholders to be paid prior to year-end.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third 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 5935686.

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. 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 in development for recurrent H3 K27M-mutant glioma. 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, results from the BICR of the 50 patient cohort of ONC201 for the treatment of recurrent H3 K27M-mutant glioma, the status of Chimerix's oncology programs, and the manufacturing, 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 current BCV manufacturing efforts may not satisfy the requirements of any procurement award; 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.

CONTACT:
Investor Relations:
Michelle LaSpaluto
919-972-7115
ir@chimerix.com

Will O'Connor
Stern Investor Relations
212-362-1200
Will@sternir.com

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,174	$ 46,989
Short-term investments, available-for-sale	96,384	31,973
Accounts receivable	53	340
Inventories	1,595	—
Prepaid expenses and other current assets	4,327	2,356
Total current assets	128,533	81,658
Long-term investments	2,035	—
Property and equipment, net of accumulated depreciation	264	214
Operating lease right-of-use assets	2,509	2,825
Other long-term assets	60	26
Total assets	$ 133,401	$ 84,723
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,792	$ 1,283
Accrued liabilities	10,498	7,250
Note payable	14,000	—
Total current liabilities	26,290	8,533
Lease-related obligations	2,525	2,814
Total liabilities	28,815	11,347
Stockholders’ equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 86,848,426 and 62,816,039 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	87	63
Additional paid-in capital	950,597	785,673
Accumulated other comprehensive loss, net	—	—
Accumulated deficit	(846,098)	(712,360)
Total stockholders’ equity	104,586	73,376
Total liabilities and stockholders’ equity	$ 133,401	$ 84,723

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Contract and grant revenue	$ 105	$ 1,591	$ 1,928	$ 4,158
Licensing revenue	2	18	5	94
Total revenues	107	1,609	1,933	4,252
Operating expenses:				
Research and development	13,820	10,018	39,480	27,545
General and administrative	4,887	3,151	13,431	9,466
Acquired in-process research and development	—	—	82,890	—
Total operating expenses	18,707	13,169	135,801	37,011
Loss from operations	(18,600)	(11,560)	(133,868)	(32,759)
Other income:				
Interest income and other, net	40	149	130	912
Net loss	(18,560)	(11,411)	(133,738)	(31,847)
Other comprehensive loss:				
Unrealized gain (loss) on debt investments, net	11	(97)	—	(2)
Comprehensive loss	$ (18,549)	$ (11,508)	$ (133,738)	$ (31,849)
Per share information:				
Net loss, basic and diluted	$ (0.21)	$ (0.18)	$ (1.59)	$ (0.51)
Weighted-average shares outstanding, basic and diluted	86,335,357	62,242,456	84,277,555	62,009,941

Chimerix Announces Positive Topline Results for ONC201 in Recurrent H3 K27M-mutant Glioma

– Blinded Independent Central Review (BICR) of ONC201 Cohort Reported 20.0% Objective Response Rate (ORR) by RANO-HGG Criteria –

– Compelling Durability of Responses with 11.2 Month Median Duration of Response (mDOR) in Addition to an 8.3 Month Median Time to Response (mTTR) –

– Additional Data to be Presented at the Society for Neuro-Oncology (SNO) Annual Meeting –

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

DURHAM, N.C., November 4, 2021 -- 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 positive topline data from its 50-patient efficacy analysis of ONC201 for the treatment of recurrent H3 K27M-mutant glioma. ONC201 is an orally administered small molecule dopamine receptor D2 (DRD2) antagonist and caseinolytic protease (ClpP) agonist for the treatment of recurrent gliomas that harbor the H3 K27M mutation.

“These results are exciting, especially for this patient population with no good systemic therapeutic options,” said Dr. Isabel Arrillaga-Romany, MD, PhD, Director of Neuro-Oncology Clinical Trials, Massachusetts General Hospital Cancer Center. “The durability of responses in patients we would otherwise expect to progress rapidly is compelling.”

“These data confirm our expectations for the potential benefit for patients with this devastating disease,” said Mike Sherman, Chief Executive Officer of Chimerix. “We look forward to sharing additional data at the SNO conference later this month. The durability of responses are complemented by the consistency of data across other clinical endpoints. We believe this represents an attractive risk – benefit for patients who otherwise receive palliative care. On behalf of the entire Chimerix team, we thank the clinical collaborators and their patients who participated in our clinical trials with the hope of improving not only their own outcomes, but also the outcomes of future patients. None of the progress we have made would be possible without their support.”

An efficacy analysis by blinded independent central review (BICR) of the registration cohort determined the overall response rate (ORR) to be 20.0% (95% Confidence Interval (CI): 10.0-33.7%) as determined by Response Assessment in Neuro-Oncology Criteria for High Grade Gliomas (RANO-HGG). The median duration of response (mDOR) was 11.2 months (95% CI: 3.8 - not reached) and the median time to response (mTTR) was 8.3 months.

The cohort for a potential registration of ONC201 was comprised of the first 50 patients enrolled across five ONC201 clinical studies who met certain criteria. These patients were two years of age or older, had measurable diffuse midline glioma, their tumor

harbored the H3 K27M mutation and had evidence of disease progression following prior therapy with at least radiation completed at least 90 days prior to enrollment, among certain other criteria.

The full BICR analysis will be presented at the Society for Neuro-Oncology (SNO) Annual Meeting on November 20, 2021. The plenary presentation will include additional supporting evidence of disease control, clinical benefit, including neurological improvements as measured by performance status, reduction in the use of corticosteroids, and an analysis of overall survival.

One serious adverse event was attributed by an investigator as possibly related to ONC201. Full safety data collection and analysis for this cohort is ongoing. Prior safety review of ONC201 identified the most commonly reported adverse events as nausea/vomiting, fatigue and decreased lymphocyte counts.
The FDA granted ONC201 Fast Track Designation for the treatment of adult recurrent H3 K27M-mutant high-grade glioma, Rare Pediatric Disease Designation for treatment of H3 K27M-mutant glioma, and Orphan Drug Designations for the treatment of glioblastoma and for the treatment of malignant glioma.

The Company plans to meet with the U.S. Food and Drug Administration in 2022 following completion of ongoing chemistry, manufacturing and controls (CMC) clinical pharmacology studies and natural disease history evaluation.

About Recurrent H3 K27M-mutant Glioma

Recurrent high-grade glioma is a form of brain cancer with a particularly poor prognosis. Pediatric patients with recurrent glioma that carries the H3 K27M mutation have an even worse prognosis. Gliomas with this mutation are considered Grade IV by the World Health Organization regardless of patient age.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss these data along with third quarter 2021 financial results 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 5935686.

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CONTACT:
Investor Relations:
Michelle LaSpaluto
919 972-7115
ir@chimerix.com

Will O'Connor
Stern Investor Relations
212-362-1200
will@sternir.com