Chimerix Reports Third Quarter 2022 Financial Results and Provides Operational Update

November 3, 2022

– ONC201 Phase 3 ACTION Study On-Track to Open Enrollment in November –

– Meeting with U.S. Food and Drug Administration (FDA) Set for Fourth Quarter –

– Strong Financial Position with ~$285 Million in Cash at September 30 –

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

DURHAM, N.C., Nov. 03, 2022 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company whose mission 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, 2022 and provided an operational update.

“Having executed an intentional strategy to narrow the focus of the company on oncology therapies most likely to have profound impact on patients and create the greatest value for shareholders, we are pleased with our strong execution and progress in the third quarter,” said Mike Sherman, Chief Executive Officer of Chimerix.

“During the quarter, we completed agreements with Biomedical Advanced Research and Development Authority (BARDA) and Emergent BioSolutions (Emergent), and booked our first product revenue with international governments which collectively secured over $270 million in non-dilutive funding to support our oncology pipeline. We also completed discussion with the FDA on the design of our global Phase 3 ACTION study of ONC201 in patients with H3 K27M-mutant glioma. We are targeting initiation of that study during the upcoming Society for Neuro Oncology Annual Meeting later this month, where we plan to have a significant presence among thought leaders in the field. With the expected initiation of the randomized Phase 3 ACTION study, we now plan to discuss the potential for an accelerated approval path with the FDA based upon the strength of the Phase 2 efficacy data, additional safety data, and the continued significant unmet need for patients with this rare brain tumor,” continued Mr. Sherman.

“With our lead program fully funded through potential commercial launch, we will continue to exercise financial discipline with regard to capital allocation,” added Mike Andriole, Chief Business Officer and Chief Financial Officer. “We are primarily relying on external, non-dilutive sources of capital to fund our earlier stage pipeline programs. As such, any acceleration of investment in these programs will follow promising data. In the meantime, we remain disciplined with spend across the organization as we complete the transition of TEMBEXA® to Emergent.”

ONC201 for Treatment of H3 K27M-Mutant Diffuse Glioma

The Phase 3 ACTION study is a randomized, double-blind, placebo-controlled, multicenter international study of ONC201 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. Participants will be randomized to receive 625mg of ONC201 once per week (the Phase 2 dosing regimen), 625mg twice per week on two consecutive days or placebo. The dose will be scaled by body weight for pediatric patients.

“We view a higher probability of success for the ACTION trial relative to other Phase 3 trials in neuro oncology,” said, Allen Melemed, M.D., Chief Medical Officer of Chimerix. “Our Phase 2 data demonstrated single agent durable responses in the relapse setting, which strictly followed FDA’s guidance for patient selection. This change in disease progression among responders included consistent and strong association between response and other clinical endpoints, including overall survival. Moving to an earlier line of treatment in this same genetically defined patient population and adding a more frequent dose arm in the ACTION study should enhance clinical activity beyond what was observed in the positive Phase 2 study results. In addition, the ACTION study design includes a number of interim readouts to claim significance in an expedited fashion.”

The Company has scheduled a meeting with the FDA to discuss the potential for an accelerated approval submission for ONC201. In addition to efficacy data previously provided to the FDA, this discussion will build on Chimerix’ recent alignment with the Agency for the Phase 3 ACTION study design and the Company’s plans to enroll this study while the accelerated approval review process is underway. New information supporting this discussion include a 211-patient safety dataset and a healthy volunteer dose escalation study, which both support the attractive safety profile of ONC201 and inform its overall benefit/risk assessment. Chimerix will incorporate FDA feedback into its decision to proceed with a New Drug Application (NDA) for accelerated approval.

TEMBEXA®

In September, Chimerix announced the closing of its sale of TEMBEXA to Emergent and received a payment of $238 million with the potential for additional milestones of up to $136.5 million. Chimerix is also eligible for 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.

Third Quarter 2022 Financial Results

For the quarter ending September 30, 2022, Chimerix reported net income of $241.4 million, or $2.75 per basic and diluted share. Chimerix recorded a net loss of $18.6 million, or $0.21 per basic and diluted share, for the third quarter of 2021.

Revenues for the third quarter of 2022 increased to $32.6 million, compared to $0.1 million for the same period in 2021 related to the international procurement sales of TEMBEXA.

Research and development expenses increased to $15.3 million for the third quarter of 2022, compared to $13.8 million for the same period in 2021 driven primarily by ongoing development expenses related to ONC201.

General and administrative expenses increased to $5.3 million for the third quarter of 2022, compared to $4.9 million for the same period in 2021.

The sale of TEMBEXA to Emergent BioSolutions, Inc. was recorded as a $229.7 million gain on a sale. Chimerix utilized net operating losses to offset federal tax liabilities and will incur nominal state tax expense.

Chimerix's balance sheet as of September 30, 2022, included approximately $285 million of capital available to fund operations, no debt and approximately 88.0 million outstanding shares of common stock.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third quarter 2022 financial results and provide a business update today at 8:30 a.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 2765632.

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, the initiation and probability of success of the Phase 3 ACTION study, the potential for accelerated approval of ONC201, and potential future payments in connection with the TEMBEXA sale transaction. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks related to the timing and completion of the Phase 3 ACTION study of ONC201; risks associated with the availability of accelerated approval for ONC201; risks that future payments in connection with the TEMBEXA sale transaction will not be made; 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)

	September, 30 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 274,261	$ 15,397
Short-term investments, available-for-sale	10,369	72,970
Accounts receivable	468	-
Inventories	-	2,760
Prepaid expenses and other current assets	6,022	4,678
Total current assets	291,120	95,805
Long-term investments	-	2,022
Property and equipment, net of accumulated depreciation	252	253
Operating lease right-of-use assets	2,078	2,404
Other long-term assets	430	56
Total assets	$ 293,880	$ 100,540

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,282	$ 2,788
Accrued liabilities	14,428	13,108
Note payable	-	14,000
Total current liabilities	17,710	29,896
Loan Fees	250	-
Lease-related obligations	1,968	2,392
Total liabilities	19,928	32,288
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding as of September 30, 2022 and December 31, 2021; no shares issued and outstanding as of September 30, 2022 and	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 88,045,127 and 86,884,266 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	88	87
Additional paid-in capital	966,370	953,782
Accumulated other comprehensive loss, net	(37)	(21)
Accumulated deficit	(692,469)	(885,596)
Total stockholders' equity	273,952	68,252
Total liabilities and stockholders' equity	$ 293,880	$ 100,540

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,	
	2022	2021	2022	2021
Revenues:				
Procurement revenue	$ 31,971	$ -	$ 31,971	$ -
Contract and grant revenue	503	105	503	1,928
Licensing revenue	81	2	536	5
Total revenues	32,555	107	33,010	1,933
Cost of goods sold	333	-	447	-
Gross Profit	32,222	107	32,563	1,933
Operating expenses:				
Research and development	15,263	13,820	52,350	39,480
General and administrative	5,313	4,887	16,785	13,431
Acquired in-process research and dvelopment	-	-	-	82,890
Total operating expenses	20,576	18,707	69,135	135,801
Income (loss) from operations	11,646	(18,600)	(36,572)	(133,868)
Other income (loss) income:				
Interest income and other, net	199	40	182	130
Gain on sale of business, net	229,670	-	229,670	-
Income (loss) before income taxes	241,515	(18,560)	193,280	(133,738)
Income tax expense	153	-	153	-
Net income (loss)	241,362	(18,560)	193,127	(133,738)
Other comprehensive income (loss):				
Unrealized gain (loss) on debt investments, net	31	11	(16)	-
Comprehensive income (loss)	$ 241,393	$ (18,549)	$ 193,111	$ (133,738)
Per share information:				
Net income (loss), basic	$ 2.75	$ (0.21)	$ 2.21	$ (1.59)
Net income (loss), diluted	$ 2.75	$ (0.21)	$ 2.17	$ (1.59)
Weighted-average shares outstanding, basic	87,634,888	86,335,357	87,388,624	84,277,555
Weighted-average shares outstanding, diluted	87,814,330	86,335,357	89,070,831	84,277,555

Source: Chimerix, Inc.