



Chimerix Reports Third Quarter 2023 Financial Results and Provides Operational Update

November 2, 2023 at 7:00 AM EDT

– Phase 3 ACTION Study Ongoing with 113 Sites Activated Across 12 Countries; Interim Survival and PFS Data on Track to Report in 2025 –

– Actively Recruiting ONC206 Dose Escalation Studies; Enrollment on Track to Complete First Half 2024 –

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

DURHAM, N.C., Nov. 02, 2023 (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, 2023 and provided an operational update.

"The third quarter was marked by strong progress across our first-in-class imipridone pipeline, including continued enrollment in our global Phase 3 ACTION study of ONC201 for the treatment of H3 K27M-mutant diffuse glioma," said Mike Andriole, Chief Executive Officer of Chimerix. "We continue to see strong interest in the ACTION study globally supported by a robust publication strategy, including the recently published front-line treatment and mechanistic data in the peer-reviewed journal *Cancer Discovery*. These data demonstrated a statistically significant increase in median overall survival (mOS) versus historical controls in a patient population with very few treatment options. As enrollment in the ACTION study continues to progress, we are also working extensively on our second-generation compound, ONC206, to identify biomarkers in patients most likely to respond in future primary efficacy studies. These early data indicate such studies may include both Central Nervous System (CNS) tumors as well as solid tumors outside of the CNS. Finally, we were delighted to join the neuro-oncology community at the European Association of Neuro-Oncology (EANO) Annual Meeting in Rotterdam last month and look forward to the upcoming Society for Neuro-Oncology (SNO) Annual Meeting in Vancouver where multiple oral presentations will highlight a series of preclinical and clinical studies of ONC201 as both monotherapy and as a potential backbone in combinatorial diffuse midline glioma (DMG) treatment settings."

ONC201 for Treatment of H3 K27M-Mutant Diffuse Glioma

The Phase 3 ACTION trial is currently enrolling patients at 113 sites in 12 countries and remains on track to report first interim overall survival data in early 2025.

The ACTION trial is enrolling patients shortly after front-line radiation therapy. The study is designed to enroll 450 patients randomized 1:1:1 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 patients <52.5kg.

In August 2023, a *Cancer Discovery* publication reported promising survival outcomes for 71 H3 K27M-DMG patients treated with ONC201. In addition, ONC201 reversed a molecular signature of the H3 K27M mutation in patient's tumor samples.

ONC206

ONC206 is a second generation ClpP agonist and DRD2 antagonist that has demonstrated monotherapy anti-cancer activity in pre-clinical models in primary CNS tumors and solid tumors outside of the CNS. Phase I dose escalation trials continue at the National Institutes of Health (NIH) and the Pacific Pediatric Neuro-Oncology Consortium (PNOC) in adult and pediatric CNS tumor patients, respectively. To date, ONC206 has been generally well tolerated with no dose limiting toxicities. The dose escalation trials have completed the once weekly dosing schedules. The study is currently dosing at more frequent dose schedules that are expected to increase the duration of therapeutic exposure.

Third Quarter 2023 Financial Results

Chimerix reported a net loss of \$24.0 million, or \$0.27 per basic and diluted share, for the third quarter of 2023. During the same period in 2022, Chimerix recorded net income of \$241.4 million, or \$2.75 per basic and diluted share.

Research and development expenses increased to \$17.4 million for the third quarter of 2023, compared to \$15.3 million for the same period in 2022.

General and administrative expenses increased to \$9.3 million for the third quarter of 2023, compared to \$5.3 million for the same period in 2022. This increase is in connection with the retirement of the CEO and transition to Chairman which resulted in a one-time non-cash expense being recognized related to historical equity grants, the vesting of which remain contingent on future service in the new role.

Chimerix's balance sheet at September 30, 2023 included \$217 million of capital available to fund operations, approximately 88.9 million outstanding shares of common stock and no outstanding debt. Chimerix expects to end the year with over \$200 million in cash and cash equivalents which is expected to be sufficient to fund operations through final ACTION study data expected in 2026.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third quarter 2023 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 5615320. 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, enrollment and interest in the Phase 3 ACTION study, the potential future studies of ONC206, the ability to generate or reproduce clinical and pre-clinical findings, and projections regarding timing of enrollment of our clinical studies, future data readouts, and the Company's cash position and runway. 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, completion and outcome of the Phase 3 ACTION study of ONC201; risks associated with repeating positive results obtained in prior preclinical or clinical studies in future studies; risks related to the clinical development of ONC206; 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)

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,118	\$ 25,842
Short-term investments, available-for-sale	180,357	191,492
Accounts receivable	11	1,040
Prepaid expenses and other current assets	6,136	9,764
Total current assets	<u>200,622</u>	<u>228,138</u>
Long-term investments	22,514	48,626
Property and equipment, net of accumulated depreciation	248	227
Operating lease right-of-use assets	1,606	1,964
Other long-term assets	292	386
Total assets	<u>\$ 225,282</u>	<u>\$ 279,341</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,502	\$ 3,034
Accrued liabilities	13,008	17,381
Total current liabilities	<u>15,510</u>	<u>20,415</u>
Line of credit commitment fee	125	250
Lease-related obligations	1,344	1,819
Total liabilities	<u>16,979</u>	<u>22,484</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding as of September 30, 2023 and December 31, 2022		
Common stock, \$0.001 par value, 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 88,891,300 and 88,054,127 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	89	88
Additional paid-in capital	986,202	970,535
Accumulated other comprehensive loss, net	(625)	(337)
Accumulated deficit	<u>(777,363)</u>	<u>(713,429)</u>
Total stockholders' equity	<u>208,303</u>	<u>256,857</u>
Total liabilities and stockholders' equity	<u>\$ 225,282</u>	<u>\$ 279,341</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Procurement revenue	\$ -	\$ 31,971	\$ -	\$ 31,971
Contract and grant revenue	11	503	271	503
Licensing revenue	-	81	49	536
Total revenues	11	32,555	320	33,010
Cost of goods sold	-	333	-	447
Gross Profit	11	32,222	320	32,563
Operating expenses:				
Research and development	17,396	15,263	53,144	52,350
General and administrative	9,304	5,313	19,431	16,785
Total operating expenses	26,700	20,576	72,575	69,135
(Loss) income from operations	(26,689)	11,646	(72,255)	(36,572)
Other income:				
Interest income and other, net	2,703	199	8,321	182
Gain on sale of business, net	-	229,670	-	229,670
(Loss) income before income taxes	(23,986)	241,515	(63,934)	193,280
Income tax expense	-	153	-	153
Net (loss) income	(23,986)	241,362	(63,934)	193,127
Other comprehensive (loss) income:				
Unrealized gain (loss) on debt investments, net	188	31	(288)	(16)
Comprehensive (loss) income	\$ (23,798)	\$ 241,393	\$ (64,222)	\$ 193,111
Per share information:				
Net (loss) income, basic	\$ (0.27)	\$ 2.75	\$ (0.72)	\$ 2.21
Net (loss) income, diluted	\$ (0.27)	\$ 2.75	\$ (0.72)	\$ 2.17
Weighted-average shares outstanding, basic	88,620,666	87,634,888	88,500,813	87,388,624
Weighted-average shares outstanding, diluted	88,620,666	87,814,330	88,500,813	89,070,831



Source: Chimerix, Inc.