Homology Medicines Reports Third Quarter 2023 Financial Results

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- Continuing to Evaluate Strategic Options for the Company and the Pipeline of Genetic Medicines, including HMI-103 -

BEDFORD, Mass., Nov. 14, 2023 (GLOBE NEWSWIRE) -- Homology Medicines, Inc. (Nasdaq: FIXX), a genetic medicines company, announced today third quarter 2023 financial results and highlighted recent updates.

Homology recently shared a summary of safety and efficacy data on the first dose cohort of the pheEDIT clinical trial evaluating the Company's HMI-103 gene editing candidate for the treatment of phenylketonuria (PKU). Despite the encouraging HMI-103 clinical data, based on the current financing environment and the anticipated clinical development timeline, Homology announced in July 2023 that it would not pursue any further development of its programs, including HMI-103, and instituted a related workforce reduction. Homology further announced that it is evaluating strategic options for the Company, its development programs, including HMI-103, and its platform technology.

The Company retained TD Cowen as its strategic financial advisor and continues to productively advance the process of assessing strategic options.

Third Quarter 2023 Financial Results

- As of September 30, 2023, Homology had approximately $103.3 million in cash, cash equivalents and short-term investments. Based on management's current projections, which include the impact of not further developing any of its research and development programs and the recent workforce reduction of approximately 80 employees, Homology believes it has sufficient cash resources to fund operations for at least one year.
- Net loss for the quarter ended September 30, 2023 was $(33.0) million or $(0.57) per share, compared to a net loss of $(33.7) million or $(0.59) per share for the quarter ended September 30, 2022.
- There was no collaboration revenue for the quarter ended September 30, 2023, compared to $0.8 million for the quarter ended September 30, 2022. Collaboration revenue for the quarter ended September 30, 2022 reflected revenue recognized under the Company's Stock Purchase Agreement with Pfizer. The Company previously granted Pfizer a right of first refusal to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103, as well as information sharing rights, both of which expired on May 9, 2023.
- Total operating expenses for the quarter ended September 30, 2023 were $31.0 million, compared to $33.7 million for the quarter ended September 30, 2022, and consisted of research and development expenses and general and administrative expenses. Operating expenses for the quarter ended September 30, 2023 also included restructuring and other charges.
- Research and development expenses for the quarter ended September 30, 2023 were $17.5 million, compared to $25.9 million for the quarter ended September 30, 2022. Research and development expenses decreased due to lower employee-related costs as a result of the workforce reduction in the third quarter of 2023, and lower clinical trial costs, partially offset by higher manufacturing and process development costs as the Company continues to wind down its remaining commitments to Oxford Biomedica Solutions, the CDMO established as a joint venture with Oxford Biomedica in March 2022.
- General and administrative expenses for the quarter ended September 30, 2023 were $6.8 million, compared to $7.8 million for the quarter ended September 30, 2022. General and administrative expenses decreased as a result of lower employee-related costs due to the workforce reduction and lower consulting and market research costs.
- Restructuring and other charges totaled $6.6 million for the quarter ended September 30,

2023 and primarily related to the workforce reduction of approximately 80 employees, effective August 3, 2023. There were no such charges in the quarter ended September 30, 2022.

About Homology Medicines, Inc.
Homology Medicines, Inc. is a clinical-stage genetic medicines company historically focused on transforming the lives of patients suffering from rare diseases by addressing the underlying cause of the disease. Homology has gene editing and gene therapy clinical-stage programs in PKU and Hunter syndrome (MPS II), a preclinical pipeline that includes a gene therapy candidate for metachromatic leukodystrophy and a GTx-mAb (vectorized antibody) candidate for paroxysmal nocturnal hemoglobinuria, as well as intellectual property on its family of 15 adeno-associated viruses (AAVHSCs). Homology is not currently pursuing further development of these programs and is pursuing strategic options for the Company and its programs and platform technology. Additionally, the Company has a twenty percent stake in Oxford Biomedica Solutions, an AAV manufacturing company based on Homology's internal process development and manufacturing formed as a joint venture between Homology and Oxford Biomedica plc. For more information, visit www.homologymedicines.com.

Forward-Looking Statements
This press release contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding: the timing and anticipated benefits and costs associated with our recent reduction in force, related corporate restructuring efforts and plans to evaluate strategic options; the expected financial and operational impacts of our restructuring initiatives; our future results of operations and financial position and the impact of the current economic environment on our business; and the sufficiency of our cash, cash equivalents and short-term investments to fund our operations. The words "believe," "may," "will," "estimate," "potential," "continue," "anticipate," "intend," "expect," "could," "would," "project," "plan," "target," and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; any financial or strategic option we pursue may not be successful; our decision to discontinue further program development efforts may not result in the anticipated savings for the Company and may adversely affect our business; our recent reduction in force undertaken to reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences as well as additional costs; should we resume development of our product candidates, potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process assuming we resume development of our product candidates; interim, topline and preliminary data may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data assuming we resume development of our product candidates; our product candidates may cause serious adverse side effects; inability to maintain our collaborations, or the failure of these collaborations; our reliance on third parties, including for the manufacture of materials for our research programs, preclinical and clinical studies assuming we resume development of our product candidates; failure to obtain U.S. or international marketing approval assuming we resume development of our product candidates; ongoing regulatory obligations; effects of significant competition; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; product liability lawsuits; securities class action litigation; the impact of the COVID-19 pandemic and general economic conditions on our business and operations, including our preclinical studies and clinical trials; failure to attract, retain and motivate qualified personnel in the future; the possibility of system failures or security breaches; risks relating to intellectual property; and significant costs incurred as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and our other filings with the Securities and Exchange Commission could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

- Financial Tables Follow -

HOMOLOGY MEDICINES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	As of	
	September 30, 2023	**December 31, 2022**
Cash, cash equivalents and short-term investments	$ 103,298	$ 175,026
Equity method investment	13,957	25,814
Assets held for sale	314	—
Property and equipment, net	—	1,078
Right-of-use assets	19,471	20,563
Other assets	3,023	5,989
Total assets	$ 140,063	$ 228,470
Accounts payable, accrued expenses and other liabilities	$ 23,514	$ 19,859
Operating lease liabilities	28,338	29,477
Deferred revenue	—	1,156
Stockholders' equity	88,211	177,978
Total liabilities and stockholders' equity	$ 140,063	$ 228,470

HOMOLOGY MEDICINES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ —	$ 802	$ 1,156	$ 2,406
Operating expenses:				
Research and development	17,519	25,854	60,489	71,202
General and administrative	6,842	7,810	23,355	29,991
Restructuring and other charges	6,640	—	6,640	—
Total operating expenses	31,001	33,664	90,484	101,193
Loss from operations	(31,001)	(32,862)	(89,328)	(98,787)
Other income:				
Gain on sale of business	—	—	—	131,249
Interest income	1,423	1,269	4,403	1,775
Total other income	1,423	1,269	4,403	133,024
Income (loss) before income taxes	(29,578)	(31,593)	(84,925)	34,237
Benefit from (provision for) income taxes	—	46	—	(816)
Loss from equity method investment	(3,376)	(2,179)	(11,917)	(4,131)
Net income (loss)	$ (32,954)	$ (33,726)	$ (96,842)	$ 29,290
Net income (loss) per share-basic	$ (0.57)	$ (0.59)	$ (1.68)	$ 0.51
Net income (loss) per share-diluted	$ (0.57)	$ (0.59)	$ (1.68)	$ 0.51
Weighted-average common shares outstanding-basic	57,853,132	57,447,192	57,788,755	57,372,399
Weighted-average common shares outstanding-diluted	57,853,132	57,447,192	57,788,755	57,901,298

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Source: Homology Medicines, Inc.