Enliven Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides a Business Update

March 13, 2025

Updated Phase 1 data for ELVN-001 expected mid-2025 as positive enrollment momentum continues

Expected monotherapy and combination data from the ELVN-002 Phase 1 trials in second half of 2025

Strong balance sheet with $313 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into mid-2027

BOULDER, Colo., Mar. 13, 2025 /PRNewswire/ -- Enliven Therapeutics, Inc. (Enliven or the Company) (Nasdaq: ELVN), a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule therapeutics, today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided a business update, including highlights of pipeline progress.

"We are very pleased with the ongoing progress we are making as a Company. We continue to hear significant enthusiasm and excitement from investigators on both of our programs. The momentum of ELVN-001 has accelerated since the data presentation at the ESH-iCMLf conference," said Sam Kintz, Co-founder and Chief Executive Officer of Enliven. "2025 is a big year for Enliven and we are excited for the upcoming program updates. We are focused on continued clinical execution and preparing for the potential start of a pivotal trial for ELVN-001 in 2026."

Recent Research and Development Highlights and Upcoming Milestones

ELVN-001 is a potent, highly selective, small molecule kinase inhibitor designed to specifically target the BCR::ABL gene fusion

- In 2024, the Company announced positive initial data from the ongoing Phase 1 clinical trial that compared favorably to the precedent Phase 1 trials for the approved BCR::ABL1 tyrosine kinase inhibitors (TKIs).
- The U.S. Food and Drug Administration (FDA) granted orphan drug designation to ELVN-001 for the treatment of chronic myeloid leukemia (CML).
- The first patient was dosed in the Phase 1 trial evaluating ELVN-001 in Japanese patients with CML (NCT06787144).
- The Company plans to report additional data from the ongoing Phase 1a/b trial in the middle of 2025.

ELVN-002 is a potent, highly selective, central nervous system (CNS) penetrant and irreversible HER2 inhibitor with activity against wild type HER2 and various HER2 mutations

- Enliven continued to enroll patients in its Phase 1 trial evaluating ELVN-002 as a monotherapy agent in patients with HER2+ and HER2 mutant tumors and its exploratory cohort in combination with Kadcyla® (an approved HER2 antibody drug conjugate) in patients with HER2+ metastatic breast cancer (MBC) (NCT05650879).
- Additionally, the Company continued to enroll patients in its Phase 1 trial evaluating ELVN-002 in combination with trastuzumab +/- chemotherapeutic agents in patients with HER2+ MBC and colorectal cancer (CRC) and began dosing patients in the Phase 1b trial specifically evaluating patients with CRC (NCT06328738).
- Enliven plans to report data from the ongoing Phase 1 trials in the second half of 2025.

Fourth Quarter and Full Year 2024 Financial Results

- **Cash Position:** As of December 31, 2024, the Company had cash, cash equivalents and marketable securities totaling $313.4 million, which is expected to provide cash runway into mid-2027.
- **Research and development (R&D) expenses:** R&D expenses were $20.7 million for the fourth quarter of 2024, compared to $17.9 million for the fourth quarter of 2023. R&D expenses were $80.8 million for the full year 2024, compared to $64.6 million for the full year 2023.
- **General and administrative (G&A) expenses:** G&A expenses for the fourth quarter of 2024 were $6.2 million, compared to $4.8 million for the fourth quarter of 2023. G&A expenses were $23.8 million for the full year 2024, compared to $19.0 million for the full year 2023.
- **Net Loss:** Enliven reported a net loss of $23.2 million for the fourth quarter of 2024, compared to a net loss of $19.4 million for the fourth quarter of 2023. Total net loss for the full year 2024 was $89.0 million, compared to $71.6 million for the full year 2023.

About Enliven Therapeutics
Enliven is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule therapeutics to help people not only live longer, but live better. Enliven aims to address existing and emerging unmet needs with a precision oncology approach that improves survival and enhances overall well-being. Enliven's discovery process combines deep insights in clinically validated biological targets and differentiated chemistry to design potentially first-in-class or best-in-class therapies. Enliven is based in Boulder, Colorado.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended) concerning Enliven and other matters that involve substantial risks and uncertainties. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations and financial position, or otherwise, based on current beliefs of the management of Enliven, as well as assumptions made by, and information currently available to, management of Enliven. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Statements that are not historical facts are forward-looking statements. Forward-looking statements in this press release include, but are not limited to, statements regarding the potential of, and plans regarding, market opportunities, and expectations regarding Enliven's programs, including ELVN-001 and ELVN-002; expected milestones for ELVN-001 and ELVN-002, including the potential timing for a start of a potential pivotal trial and the expected timing of data from the clinical trials of ELVN-001 and ELVN-002, including updated data from the Phase 1 trial evaluating ELVN-001 in patients with CML and the Phase 1 trials in ELVN-002; statements relating to Enliven's expected cash runway; and statements by Enliven's Co-founder and Chief Executive Officer. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various risks and uncertainties, including, without limitation: the limited operating history of Enliven; the ability to advance product candidates through clinical development; the ability to obtain regulatory approval for, and ultimately commercialize or license, product candidates; the outcome of preclinical testing and early clinical trials for product candidates and the potential that the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials; Enliven's limited resources; the risk of failing to demonstrate safety and efficacy of product candidates; Enliven's limited experience as a company in designing and conducting clinical trials; the potential for interim, topline, and preliminary data from Enliven's preclinical studies and clinical trials to materially change from the final data; potential delays or difficulties in the enrollment or maintenance of patients in clinical trials; developments relating to Enliven's competitors and its industry, including competing product candidates and therapies; the decision to develop or seek strategic collaborations to develop Enliven's current or future product candidates in combination with other therapies and the cost of combination therapies; the ability to attract, hire, and retain highly skilled executive officers and employees; the ability of Enliven to protect its intellectual property and proprietary technologies; the scope of any patent protection Enliven obtains or the loss of any of Enliven's patent protection; reliance on third parties, including medical institutions, contract manufacturing organizations, contract research organizations and strategic partners; geo-political developments, general market or macroeconomic conditions; Enliven's ability to obtain additional capital to fund Enliven's general corporate activities and to fund Enliven's research and development; and other risks and uncertainties, including those more fully described in Enliven's filings with the Securities and Exchange Commission (SEC), which may be found in the section titled "Risk Factors" in Enliven's Annual and Quarterly Reports on Form 10-K and 10-Q filed with the SEC and in Enliven's future reports to be filed with the SEC. Except as required by applicable law, Enliven undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference into this press release.

Enliven Therapeutics, Inc.
Selected Condensed Consolidated Financial Information
(in thousands, except per share data)
(unaudited)

Statements of Operations	**Three Months Ended December 31,**		**Year Ended December 31,**	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 20,724	$ 17,905	$ 80,778	$ 64,574
General and administrative	6,172	4,824	23,776	18,955
Total operating expenses	26,896	22,729	104,554	83,529
Loss from operations	(26,896)	(22,729)	(104,554)	(83,529)
Other income (expense), net	3,716	3,359	15,530	11,945
Net loss	$ (23,180)	$ (19,370)	$ (89,024)	$ (71,584)
Net loss per share, basic and diluted	$ (0.46)	$ (0.47)	$ (1.89)	$ (2.01)
Weighted-average shares outstanding, basic and diluted	49,858	41,128	47,073	35,546

Balance Sheets	**December 31,**	
	2024	**2023**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 313,440	$ 253,148
Restricted cash	54	54
Prepaid expenses and other current assets	4,633	2,949
Contingent value right asset	—	10,000
Total current assets	318,127	266,151
Property and equipment, net	458	742
Operating lease right-of-use assets	—	320
Deferred offering costs	—	563
Other long-term assets	7,175	4,091

Total assets	$ 325,760	$ 271,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,342	$ 532
Accrued expenses and other current liabilities	14,573	15,362
Contingent value right liability	—	10,000
Total current liabilities	15,915	25,894
Long-term liabilities	—	67
Total liabilities	15,915	25,961
Stockholders' equity	309,845	245,906
Total liabilities and stockholders' equity	$ 325,760	$ 271,867

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