Enliven Therapeutics Reports First Quarter Financial Results and Provides a Business Update

May 14, 2025

Updated data from the Phase 1 ENABLE clinical trial of ELVN-001 in CML to be presented at the EHA 2025 Congress in June

EHA abstract reported cumulative MMR rate of 44% (16 of 36) by 24 weeks with 26% (7 of 27) of patients achieving MMR by 24 weeks, and ELVN-001 remains well-tolerated with 74 patients enrolled

Enliven to host a webcast and conference call following the oral presentation at EHA on Friday, June 13, at 1:30 p.m. ET

Strong balance sheet with $290 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into late 2027

BOULDER, Colo., May 14, 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 first quarter ended March 31, 2025, and provided a business update, including highlights of pipeline progress.

"We are very pleased with the continued progress of ELVN-001 and the data that was just released in the EHA abstract. We continue to gain confidence and momentum in the program as the efficacy, safety and tolerability data consistently compare favorably to the approved BCR::ABL inhibitors. We are excited to share further updated data at EHA next month," said Sam Kintz, Co-founder and Chief Executive Officer of Enliven. "Looking towards the rest of the year, we remain focused on clinical execution as we prepare 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

- Today, the Company announced positive updated data from the ongoing ENABLE Phase 1 clinical trial evaluating ELVN-001 in patients with previously treated chronic myeloid leukemia (CML) (NCT05304377) in an abstract that was accepted for an oral presentation at the European Hematology Association (EHA) Congress.
    - As of the cutoff date for the abstract (January 21, 2025), 74 patients were enrolled in the trial across dose levels from 10-160 mg daily, and the vast majority of patients (82%) remain on study with a median treatment duration of ~26 weeks.
    - 16 of 36 (44%) evaluable patients were in major molecular response (MMR) by 24 weeks, with 7 of 27 (26%) achieving and 9 of 9 (100%) maintaining MMR.
    - ELVN-001 continues to demonstrate a favorable safety and tolerability profile, consistent with its selective kinase profile.
    - These data continue to compare favorably to precedent Phase 1 trials of the approved BCR::ABL1 tyrosine kinase inhibitors (TKIs), particularly given the more heavily pre-treated patient population in the ELVN-001 clinical trial.
- An oral presentation will be delivered at the EHA 2025 Congress, taking place June 12–15 in Milan, Italy, and virtually, and will highlight updated results, including data from additional patients and longer treatment duration.
- Enliven will also host a webcast and conference call at 1:30 p.m. ET on Friday, June 13, 2025, to discuss the updated data. Details of the webcast are posted on the Upcoming Events page of the Company's website.

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

- The Company dosed the first patient in its Phase 1 exploratory cohort evaluating ELVN-002 in combination with trastuzumab deruxtecan (NCT05650879) and progressed its Phase 1 trial evaluating ELVN-002 in combination with trastuzumab in HER2+ colorectal cancer (NCT06328738).
- To prioritize the advancement of ELVN-001 and its upcoming pivotal trial, the Company plans to explore strategic alternatives for the ELVN-002 program and does not intend to pursue its development beyond 2025, which is expected to extend cash runway into late 2027.

First Quarter 2025 Financial Results

- **Cash Position:** As of March 31, 2025, the Company had cash, cash equivalents and marketable securities totaling $289.6 million, which is expected to provide cash runway into late 2027.
- **Research and development (R&D) expenses:** R&D expenses were $24.9 million for the first quarter of 2025, compared to $20.0 million for the first quarter of 2024.
- **General and administrative (G&A) expenses:** G&A expenses were $6.8 million for the first quarter of 2025, compared to $6.0 million for the first quarter of 2024.

- **Net Loss:** Enliven reported a net loss of $28.5 million for the first quarter of 2025, compared to a net loss of $22.7 million for the first quarter of 2024.

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 condition, 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; Enliven's pipeline of product candidates; expected milestones for ELVN-001, including the expected timing of reporting data from the Phase 1 ENABLE clinical trial of ELVN-001 in CML and the timing for the potential start of a pivotal trial for ELVN-001; statements relating to Enliven's plans to pursue strategic alternatives for ELVN-002 and to discontinue the program beyond 2025; 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 ability of Enliven to successfully pursue strategic alternatives for ELVN-002; 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.

Head-to-Head Comparisons
The Company has not performed any head-to-head trials for ELVN-001. As a result, the data referenced in this press release is derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, conclusions from cross-trial comparisons cannot be made.

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

Statements of Operations	**Three Months Ended March 31,**	
	2025	**2024**
Operating expenses:		
Research and development	$ 24,895	$ 19,970
General and administrative	6,798	6,017
Total operating expenses	31,693	25,987
Loss from operations	(31,693)	(25,987)
Other income (expense), net	3,149	3,249
Net loss	$ (28,544)	$ (22,738)
Net loss per share, basic and diluted	$ (0.57)	$ (0.54)
Weighted-average shares outstanding, basic and diluted	50,051	42,046

Balance Sheets	**March 31,**	**December 31,**

	2025	2024
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 289,555	$ 313,440
Restricted cash	—	54
Prepaid expenses and other current assets	4,763	4,633
Total current assets	294,318	318,127
Property and equipment, net	404	458
Operating lease right-of-use assets	651	—
Other long-term assets	7,197	7,175
Total assets	$ 302,570	$ 325,760
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,562	$ 1,342
Accrued expenses and other current liabilities	12,410	14,573
Total current liabilities	13,972	15,915
Long-term liabilities	302	—
Total liabilities	14,274	15,915
Stockholders' equity	288,296	309,845
Total liabilities and stockholders' equity	$ 302,570	$ 325,760

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