Enliven Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides a Business Update

March 3, 2026

Reported positive initial Phase 1b data for ELVN-001 in CML

Initiation of the Phase 3 ENABLE-2 pivotal trial of ELVN-001 expected in the second half of 2026

Key data readout, regulatory interactions, and operational catalysts throughout 2026

Strong balance sheet with $463 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into the first half of 2029

BOULDER, Colo., March 3, 2026 /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, 2025, and provided a business update, including highlights of positive initial data from the ongoing Phase 1b ENABLE clinical trial evaluating ELVN-001 in patients with chronic myeloid leukemia (CML) that is relapsed, refractory or intolerant to available tyrosine kinase inhibitors (TKIs) (NCT05304377).

"2025 was a year of meaningful progress as we advanced ELVN-001 toward a Phase 3 pivotal clinical trial," said Rick Fair, Chief Executive Officer of Enliven. "As we move into 2026, we're entering one of the most active and transformative periods in Enliven's history – with an important data readout, key regulatory interactions, and the planned initiation of our ENABLE-2 pivotal trial. We are focused on execution to demonstrate ELVN-001's potential as a best-in-class ATP-competitive inhibitor for people living with CML."

ELVN-001 Program Highlights

ELVN-001 is a potent, highly selective, potentially best-in-class small molecule kinase inhibitor designed to specifically target the BCR::ABL gene fusion, the oncogenic driver for patients with CML.

- The Company announced positive initial Phase 1b data for ELVN-001 in patients with CML.
  - As of the cutoff date of December 22, 2025, 60 patients were enrolled in the initial cohorts of the Phase 1b trial. Patients were first enrolled in the 80 mg once daily (QD) cohort. Subsequent patients were randomized to either 60 mg QD or 120 mg QD.
  - Patients enrolled were heavily pretreated, consistent with patients from previously reported datasets. In these 60 patients:
    - 53% of patients received four or more unique prior TKIs.
    - 67% of patients received prior asciminib and 32% received prior ponatinib.
  - Despite the heavily pretreated patient population, the efficacy data below, which shows MMR rates by 24 weeks, highlights that ELVN-001 continues to demonstrate the profile of a best-in-class ATP-competitive inhibitor.

Dose (number of patients)	80 mg QD (n=19)	60/120 mg QD (n=41)
Cumulative Major Molecular Response (MMR)	47% (n=19)	69% (n=26)
Achieved MMR	38% (n=16)	53% (n=17)
Maintained MMR	100% (n=3)	100% (n=9)
Deep Molecular Response (DMR)	16% (n=19)	35% (n=26)

- Upcoming ELVN-001 Milestones
  - Mid-year presentation of additional Phase 1 data from the ongoing ENABLE trial
  - Regulatory alignment with the FDA on dose selection and Phase 3 trial design
  - Initiation of ENABLE-2, the Phase 3 clinical trial of ELVN-001, in the second half of 2026

Additional Company Updates

- The strength of the ELVN-001 data to-date and the Company's clear path forward to the initiation of its planned Phase 3 pivotal trial and potential commercialization have driven recent leadership and Board changes, including the appointment of Rick Fair as Chief Executive Officer in December 2025 and the addition of Scott Garland to the Board in January 2026.
- These changes underscore Enliven's commitment to aligning experienced leadership and governance with its transition into late-stage development and future commercialization.

Fourth Quarter and Full Year 2025 Financial Results

- **Cash Position:** As of December 31, 2025, the Company had cash, cash equivalents and marketable securities totaling $462.6 million, which is expected to provide cash runway into the first half of 2029.
- **Research and development (R&D) expenses:** R&D expenses were $21.2 million for the fourth quarter of 2025, compared to $20.7 million for the fourth quarter of 2024. R&D expenses were $85.9 million for the full year 2025, compared to $80.8 million for the full year 2024.
- **General and administrative (G&A) expenses:** G&A expenses for the fourth quarter of 2025 were $13.0 million, compared to $6.2 million for the fourth quarter of 2024, mainly driven by stock-based compensation related to the CEO transition announced in December 2025. G&A expenses were $33.8 million for the full year 2025, compared to $23.8 million for the full year 2024.

- **Net Loss:** Enliven reported a net loss of $29.7 million for the fourth quarter of 2025, compared to a net loss of $23.2 million for the fourth quarter of 2024. Total net loss for the full year 2025 was $103.7 million, compared to $89.0 million for the full year 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 medicine approach that improves survival and enhances overall well-being. Enliven's discovery process combines deep insights into clinically validated biological targets and differentiated chemistry to design potentially first-in-class or best-in-class therapies. Enliven is based in Boulder, Colorado. To learn more, visit www.enliventherapeutics.com and connect with us on LinkedIn and X.

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 ELVN-001 program; expected milestones for ELVN-001, including the potential timing for the presentation of additional Phase 1 data from the ongoing ENABLE trial, the potential timing of regulatory and operational catalysts including regulatory alignment with the FDA on dose selection and Phase 3 trial design, and potential timing of the initiation of ENABLE-2; statements regarding the potential commercialization of ELVN-001; Enliven's expected cash runway; and statements by Enliven's 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 potential for the results of the ongoing or any future clinical trial of ELVN-001 to differ from the results from earlier trials of ELVN-001; the risk of delays in completing the ongoing ENABLE trial or initiation of a Phase 3 trial of ELVN-001; risks associated with unexpected events during the remainder of the ongoing ENABLE trial, including serious adverse events, toxicities or other undesirable side effects; the risk of difficulties in enrolling or maintaining patients in clinical trials of ELVN-001; 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; or the risk that FDA disagrees with Enliven's clinical trial design or Enliven's interpretation of the data; the risk that regulatory authorities may require Enliven to develop and obtain approval for a companion diagnostic in connection with the approval of a product candidate; 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; 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,**	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 21,245	$ 20,724	$ 85,856	$ 80,778
General and administrative	13,040	6,172	33,802	23,776
Total operating expenses	34,285	26,896	119,658	104,554
Loss from operations	(34,285)	(26,896)	(119,658)	(104,554)
Other income (expense), net	4,618	3,716	15,964	15,530
Net loss	$ (29,667)	$ (23,180)	$ (103,694)	$ (89,024)
Net loss per share, basic and diluted	$ (0.48)	$ (0.46)	$ (1.83)	$ (1.89)
Weighted-average shares outstanding, basic and diluted	62,213	49,858	56,664	47,073

Balance Sheets	**December 31,**	
	2025	**2024**
Assets		

Current assets:		
Cash, cash equivalents and marketable securities	$ 462,621	$ 313,440
Restricted cash	—	54
Prepaid expenses and other current assets	12,257	4,633
Total current assets	474,878	318,127
Property and equipment, net	34	458
Operating lease right-of-use assets	383	—
Deferred offering costs	217	—
Other long-term assets	656	7,175
Total assets	$ 476,168	$ 325,760
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,159	$ 1,342
Accrued expenses and other current liabilities	14,409	14,573
Total current liabilities	16,568	15,915
Total liabilities	16,568	15,915
Stockholders' equity	459,600	309,845
Total liabilities and stockholders' equity	$ 476,168	$ 325,760

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