UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 13, 2025

Enliven Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39247**	**81-1523849**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
6200 Lookout Road Boulder, Colorado		**80301**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: 720 647-8519

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ELVN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 13, 2025, Enliven Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2025. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release issued on August 13, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Enliven Therapeutics, Inc.

Date: August 13, 2025

By: /s/ Samuel Kintz
Name: Samuel Kintz
Title: President and Chief Executive Officer

Exhibit 99.1

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

Announced positive data from the Phase 1 clinical trial of ELVN-001 in CML, reporting a cumulative MMR rate of 47% with 32% of patients achieving MMR by 24 weeks and demonstrating a favorable safety and tolerability profile across all dose levels

Strong balance sheet with $491 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into the first half of 2029

BOULDER, Colo., August 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 second quarter ended June 30, 2025, and provided a business update, including highlights of pipeline progress.

“We made tremendous progress this quarter. Notably, we reported updated positive clinical data for ELVN-001, which continue to compare favorably to precedent Phase 1 trials of approved BCR::ABL1 TKIs despite being evaluated in a more heavily pre-treated patient population,” said Sam Kintz, Co-founder and Chief Executive Officer of Enliven. “These results reinforce our belief that ELVN-001 could ultimately compete across all lines of CML therapy based on its differentiated efficacy, tolerability and convenience – attributes that position it to be a potential best-in-class therapy for people living with CML. Building on the strength of these findings, we expect to initiate our first Phase 3 pivotal trial in 2026 and remain confident in ELVN-001’s potential within the CML treatment landscape. We also strengthened our balance sheet through our recent public offering, which generated gross proceeds of approximately $230 million and extended our cash runway into the first half of 2029.”

Pipeline Updates

ELVN-001 is a potent, highly selective, small molecule kinase inhibitor designed to specifically target the BCR::ABL gene fusion, the oncogenic driver for patients with chronic myeloid leukemia (CML).

- In June 2025, the Company announced positive updated data from the ongoing ENABLE Phase 1 clinical trial evaluating ELVN-001 in patients with previously treated CML (NCT05304377) in an oral presentation at the European Hematology Association (EHA) Congress.
  - As of the April 28, 2025, cutoff date, 25 of 53 (47%) evaluable patients were in major molecular response (MMR) by 24 weeks, with 13 of 41 (32%) achieving and 12 of 12 (100%) maintaining MMR.
  - ELVN-001 remains well-tolerated across all evaluated doses.
- These data continued to compare favorably to precedent Phase 1 MMRs for approved BCR::ABL1 tyrosine kinase inhibitors (TKIs), particularly given the more heavily pretreated patient population in the ELVN-001 clinical trial.
  - Specifically, the achieved MMR rate by 24 weeks of 32% compares favorably with historical data from less heavily pretreated patients receiving asciminib, which showed achieved MMR rates of 24% in the Phase 1 trial and 25% in the ASCEMBL Phase 3 trial.

- The Company plans to initiate a Phase 3 pivotal trial in 2026.

Second Quarter 2025 Financial Results

- **Cash Position:** As of June 30, 2025, the Company had cash, cash equivalents and marketable securities totaling $490.5 million, which is expected to provide cash runway into the first half of 2029.
- **Research and development (R&D) expenses:** R&D expenses were $21.5 million for the second quarter of 2025, compared to $18.8 million for the second quarter of 2024.
- **General and administrative (G&A) expenses:** G&A expenses were $7.1 million for the second quarter of 2025, compared to $5.8 million for the second quarter of 2024.
- **Net Loss:** Enliven reported a net loss of $25.3 million for the second quarter of 2025, compared to a net loss of $20.0 million for the second 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 ELVN-001 program; Enliven’s pipeline of product candidates; expected milestones for ELVN-001, including the expected timing for the potential start of a Phase 3 pivotal trial for ELVN-001; 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.

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

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.

Contact
Investors
ir@enliventherapeutics.com

Media
media@enliventherapeutics.com

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

Statements of Operations	**Three Months Ended June 30,**		**Six Months Ended June 30,**	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 21,491	$ 18,826	$ 46,386	$ 38,796
General and administrative	7,093	5,777	13,891	11,794
Total operating expenses	28,584	24,603	60,277	50,590
Loss from operations	(28,584)	(24,603)	(60,277)	(50,590)
Other income (expense), net	3,249	4,653	6,398	7,902
Net loss	$ (25,335)	$ (19,950)	$ (53,879)	$ (42,688)
Net loss per share, basic and diluted	$ (0.49)	$ (0.41)	$ (1.05)	$ (0.95)
Weighted-average shares outstanding, basic and diluted	52,105	48,075	51,084	45,060

Balance Sheets	**June 30, 2025**	**December 31, 2024**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 490,503	$ 313,440
Restricted cash	—	54
Prepaid expenses and other current assets	5,119	4,633
Total current assets	495,622	318,127
Property and equipment, net	462	458
Operating lease right-of-use assets	564	—
Other long-term assets	7,239	7,175
Total assets	$ 503,887	$ 325,760
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,351	$ 1,342
Accrued expenses and other current liabilities	12,860	14,573
Total current liabilities	15,211	15,915
Long-term liabilities	204	—
Total liabilities	15,415	15,915
Stockholders' equity	488,472	309,845
Total liabilities and stockholders' equity	$ 503,887	$ 325,760