
**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 05, 2026

Enliven Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39247
(Commission File Number)

81-1523849
(IRS Employer
Identification No.)

**205 Park Road
Burlingame, California**
(Address of principal executive offices)

94010
(Zip Code)

Registrant's telephone number, including area code: 650 547-5814

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 5, 2026, Enliven Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2026. 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 5, 2026
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 5, 2026

By: /s/ Richard Fair
Name: Richard Fair
Title: President and Chief Executive Officer

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

Announced positive Phase 1 clinical data for ELVN-001 in CML, demonstrating encouraging ELVN-001 efficacy data and a favorable safety and tolerability profile

Reached alignment with the FDA on key Phase 3 trial design components

Strong balance sheet with \$895 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into 2030

BURLINGAME, Calif., Aug. 5, 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 second quarter ended June 30, 2026, and provided a business update.

"The second quarter was an important period for Enliven as we announced compelling updated clinical data for ELVN-001, reached alignment with the FDA on key components of the ENABLE-2 Phase 3 2L+ trial design, and significantly strengthened our balance sheet," said Rick Fair, Chief Executive Officer of Enliven. "The updated Phase 1 data support ELVN-001's potential to become a best-in-class treatment for patients living with CML. Combined with our recent regulatory and financial progress, we are well positioned to initiate ENABLE-2 later this year and rapidly advance ELVN-001 across all lines of CML therapy."

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::ABL1 gene fusion, the oncogenic driver for patients living with chronic myeloid leukemia (CML).

- In June 2026, the Company [announced](#) positive data from the ongoing ENABLE Phase 1 clinical trial evaluating ELVN-001 in patients with previously treated CML ([NCT05304377](#)). The data were presented in an oral presentation at the European Hematology Association (EHA) Congress by Dennis Kim, M.D., Professor of Medicine, Department of Medical Oncology and Hematology at the Princess Margaret Cancer Centre, Canada. Highlights include:
 - o 61% overall major molecular response (MMR) and 48% MMR achievement by 24 weeks in the 80 mg once daily (QD) Phase 1b cohort.
 - o Response rates were higher in earlier-line patients, with 67% overall MMR and 55% achieving MMR by 24 weeks among patients with only one or two prior unique tyrosine kinase inhibitors (TKIs).
 - o Patients previously treated with asciminib achieved response rates comparable to the overall efficacy-evaluable population.
 - o Favorable safety and tolerability profile with 161 patients enrolled and a median treatment duration of 35 weeks, as of the March 10, 2026 cutoff.
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- Key outcomes from the End-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA):
 - 80 mg QD selected as the recommended dose for Phase 3 ENABLE-2 trial.
 - ENABLE-2 is expected to enroll patients with CML previously treated with one or more TKIs, and to be randomized to receive either ELVN-001 or physician's choice of an ATP-competitive TKI.
 - Additional details of the Phase 3 trial design are expected to be finalized following further discussions with the FDA, including at a planned End-of-Phase 2 meeting anticipated in the third quarter of 2026.
- FDA granted Fast Track Designation to ELVN-001.
- Collectively, these data and regulatory milestones continue to support advancement of ELVN-001 into the planned ENABLE-2 Phase 3 trial, which the Company expects to initiate in the second half of 2026.

Second Quarter 2026 Financial Results

- **Cash position:** As of June 30, 2026, the Company had cash, cash equivalents and marketable securities totaling \$895.2 million, which is expected to provide cash runway into 2030.
- **Research and development (R&D) expenses:** R&D expenses were \$29.0 million for the second quarter of 2026, compared to \$21.5 million for the second quarter of 2025.
- **General and administrative (G&A) expenses:** G&A expenses were \$8.2 million for the second quarter of 2026, compared to \$7.1 million for the second quarter of 2025.
- **Net loss:** Enliven reported a net loss of \$32.5 million for the second quarter of 2026, compared to a net loss of \$25.3 million for the second quarter of 2025.

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 Burlingame, California. 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 Enliven's management, as well as assumptions made by, and information currently available to, Enliven's management. 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 profile, safety, tolerability,

efficacy and potential best-in-class profile of ELVN-001; the interpretation of data from the ongoing ENABLE trial and regulatory milestones supporting the advancement of ELVN-001 into the planned ENABLE-2 Phase 3 trial, and the timing of such advancement; the continued conduct, design, objectives, endpoints, and future clinical evaluation of ELVN-001, including the planned ENABLE-2 Phase 3 trial, the potential timing of initiation of ENABLE-2; the potential timing for advancing ELVN-001 across all lines of CML therapy; the potential timing and outcome of further FDA discussions and the finalization of additional Phase 3 trial design details, including a planned End-of-Phase 2 meeting and the timing of such meeting; 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 interim, topline and preliminary results from Enliven's clinical trials to materially change as additional patient data become available or following more comprehensive review; the potential for results from the ongoing or any future clinical trial of ELVN-001 to differ from the results of earlier trials of ELVN-001; ELVN-001 failing to demonstrate sufficient safety, efficacy, tolerability, durability, differentiated attributes or therapeutic benefit in current or future clinical trials; risks associated with unexpected events during the remainder of the ENABLE trial including serious adverse events, toxicities, dose reductions, discontinuations or other undesirable side effects; delays or difficulties in recruiting, enrolling or maintaining patients in ELVN-001 clinical trials; the risks of delays in completing the ongoing ENABLE trial or initiating ENABLE-2; Enliven failing to complete the ongoing ENABLE trial, to present additional data, to initiate ENABLE-2 or to advance ELVN-001 through clinical development; regulatory authorities disagreeing with Enliven's clinical trial design, dose selection, endpoints or interpretation of data, or requiring additional studies or diagnostics; developments relating to Enliven's competitors and industry which may affect the development or potential market opportunity for ELVN-001; and the potential inability of Enliven to obtain regulatory approval for, or ultimately commercialize or license, ELVN-001 or other product candidates; Enliven's ability to obtain or maintain the benefits associated with Fast Track designation; Enliven's limited resources; 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 more fully described in Enliven's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Enliven's Annual and Quarterly Reports on Form 10-K and Form 10-Q filed with the SEC and in Enliven's future SEC filings. 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.

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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 28,996	\$ 21,491	\$ 49,683	\$ 46,386
General and administrative	8,213	7,093	15,349	13,891
Total operating expenses	37,209	28,584	65,032	60,277
Loss from operations	(37,209)	(28,584)	(65,032)	(60,277)
Other income (expense), net	4,724	3,249	8,920	6,398
Net loss	\$ (32,485)	\$ (25,335)	\$ (56,112)	\$ (53,879)
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.49)	\$ (0.87)	\$ (1.05)
Weighted-average shares outstanding, basic and diluted	66,172	52,105	64,495	51,084

Balance Sheets

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 895,155	\$ 462,621
Prepaid expenses and other current assets	12,184	12,257
Total current assets	907,339	474,878
Property and equipment, net	140	34
Operating lease right-of-use assets	1,502	383
Deferred offering costs	—	217
Other long-term assets	1,242	656
Total assets	\$ 910,223	\$ 476,168
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 371	\$ 2,159
Accrued expenses and other current liabilities	13,790	14,409
Total current liabilities	14,161	16,568
Long-term liabilities	913	—
Total liabilities	15,074	16,568
Stockholders' equity	895,149	459,600
Total liabilities and stockholders' equity	\$ 910,223	\$ 476,168

