# 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): November 05, 2026**

# 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.)** |
| **205 Park Road Burlingame, California** | | **94010** |
| **(Address of principal executive offices)** | | **(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 November 5, 2026, Enliven Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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 November 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: November 5, 2026

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

**Exhibit 99.1**

# Enliven Therapeutics Reports Third Quarter 2026 Financial Results and Provides a Business Update

*Reached alignment with the FDA on the final design of the ENABLE-2 pivotal Phase 3 trial*

*On track to initiate ENABLE-2 before year-end 2026*

*Strong balance sheet with $884 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into 2030*

BURLINGAME, Calif., Nov. 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 third quarter ended September 30, 2026, and provided a business update.

“This quarter marked an important milestone for Enliven as we reached alignment with the FDA on the final design of ENABLE-2, providing a clear path to initiate our first pivotal trial,” said Rick Fair, Chief Executive Officer of Enliven. “The compelling ENABLE data presented at EHA in June generated strong engagement across the medical community, and we are encouraged by the enthusiasm from physicians and investigators as we prepare to initiate ENABLE-2. As we approach year-end, we remain confident in relcobatinib's potential to become a best-in-class therapy for patients with CML and are focused on executing our Phase 3 development program.”

**Relcobatinib Updates**

- The United States Adopted Names (USAN) Council adopted relcobatinib as the nonproprietary name for ELVN-001.
- The Company announced that it reached alignment with the U.S. Food and Drug Administration (FDA) on the final design of the ENABLE-2 pivotal trial of relcobatinib in patients with previously treated chronic myeloid leukemia (CML).
- Clinical data for relcobatinib from the Phase 1 ENABLE trial were featured in encore oral presentations at the meetings of the Society of Hematologic Oncology (SOHO), the International CML Foundation (ESH-iCMLf), the Japanese Society of Hematology (JSH) and the German Society for Hematology and Medical Oncology (DGHO), reflecting continued enthusiasm for its clinical profile.
- Preclinical data published in the peer-reviewed journal *Leukemia* demonstrated relcobatinib’s unique binding mode, high selectivity for BCR::ABL1 and activity against a broad range of clinically relevant tyrosine kinase inhibitor (TKI)-resistant mutations, supporting its potential as a best-in-class TKI for CML.
- The Company remains on track to initiate ENABLE-2 before year-end 2026.

**Additional Company Updates**

- Enliven appointed Kristine Ball, an accomplished biopharmaceutical executive, to its Board of Directors.
- Management will participate at the following investor conferences:
  - Guggenheim Healthcare Innovation Conference, November 9-11, Boston, MA (Fireside Chat and 1x1 Meetings)
  - Stifel Healthcare Conference, November 10-12, New York, NY (1x1 Meetings)
  - Jefferies Global Healthcare Conference, November 16-19, London, UK (Fireside Chat and 1x1 Meetings)
    - The fireside chat will be webcast live and can be accessed by visiting the investor relations section of the Company's website at https://ir.enliventherapeutics.com/. The webcast will be archived for a period of 90 days following the conclusion of the live event.

**Third Quarter 2026 Financial Results**

- **Cash position:** As of September 30, 2026, the Company had cash, cash equivalents and marketable securities totaling $884.4 million, which is expected to provide cash runway into 2030.
- **Research and development (R&D) expenses:** R&D expenses were $28.0 million for the third quarter of 2026, compared to $18.2 million for the third quarter of 2025.
- **General and administrative (G&A) expenses:** G&A expenses were $8.0 million for the third quarter of 2026, compared to $6.9 million for the third quarter of 2025.
- **Net loss:** Enliven reported a net loss of $27.7 million for the third quarter of 2026, compared to a net loss of $20.1 million for the third quarter of 2025.

**About Relcobatinib (ELVN-001)**

Relcobatinib (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 CML. As a highly selective active-site TKI, relcobatinib has a mechanism of action that is complementary to allosteric BCR::ABL1 inhibitors, which may play an increasingly important role in the standard of care. Relcobatinib was also designed to have activity against the T315I mutation, the most common BCR::ABL1 mutation, which confers resistance to nearly all approved TKIs, as well as activity against mutations known to confer resistance to allosteric BCR::ABL1 inhibitors.

**About the ENABLE-2 Trial**

ENABLE-2 is a planned randomized Phase 3 trial of relcobatinib in adults with CML previously treated with one or more TKIs. The trial is expected to enroll approximately 450 patients, who will be randomized 1:1 to receive relcobatinib 80 mg once daily or an investigator-selected second-generation TKI (dasatinib, nilotinib, or bosutinib). The primary endpoint is major molecular response (MMR) at Week 24, which could support accelerated approval, with MMR at Week 96 serving as the key secondary endpoint that could support full approval.

**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, activity, selectivity, safety, tolerability, efficacy, differentiated attributes, therapeutic benefit and potential best-in-class profile of relcobatinib; the interpretation of data from the ongoing ENABLE trial, including MMR rate, safety and tolerability data; the timing, content and availability of additional clinical data and presentation materials; the continued conduct, design, objectives, endpoints, dose selection and future clinical evaluation of relcobatinib, including the planned ENABLE-2 Phase 3 trial, the potential timing of initiation of ENABLE-2, the potential timing and outcome of the Phase 3 trial; 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 relcobatinib to differ from the results of earlier trials of relcobatinib; relcobatinib 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 relcobatinib 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 relcobatinib 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 relcobatinib; the potential inability of Enliven to obtain regulatory approval for, or ultimately commercialize or license, relcobatinib or other product candidates; 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; geopolitical developments, general market or macroeconomic conditions; the risk that Enliven's cash runway estimate is based on assumptions that may prove to be wrong and that Enliven may use its capital resources sooner than it expects; 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 September 30,** | | **Nine Months Ended September 30,** | |
|---|---|---|---|---|
| | **2026** | **2025** | **2026** | **2025** |
| Operating expenses: | | | | |
| Research and development | $ 28,024 | $ 18,225 | $ 77,707 | $ 64,611 |
| General and administrative | 8,021 | 6,871 | 23,370 | 20,762 |
| Total operating expenses | 36,045 | 25,096 | 101,077 | 85,373 |
| Loss from operations | (36,045) | (25,096) | (101,077) | (85,373) |
| Other income (expense), net | 8,342 | 4,948 | 17,262 | 11,346 |
| Net loss | $ (27,703) | $ (20,148) | $ (83,815) | $ (74,027) |
| Net loss per share, basic and diluted | $ (0.36) | $ (0.32) | $ (1.21) | $ (1.35) |
| Weighted-average shares outstanding, basic and diluted | 77,982 | 62,094 | 69,040 | 54,794 |

| **Balance Sheets** | **September 30, 2026** | **December 31, 2025** |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash, cash equivalents and marketable securities | $ 884,351 | $ 462,621 |
| Prepaid expenses and other current assets | 10,405 | 12,257 |
| Total current assets | 894,756 | 474,878 |
| Property and equipment, net | 201 | 34 |
| Operating lease right-of-use assets | 1,306 | 383 |
| Deferred offering costs | — | 217 |
| Other long-term assets | 962 | 656 |
| Total assets | $ 897,225 | $ 476,168 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,730 | $ 2,159 |
| Accrued expenses and other current liabilities | 16,743 | 14,409 |
| Total current liabilities | 19,473 | 16,568 |
| Long-term liabilities | 805 | — |
| Total liabilities | 20,278 | 16,568 |
| Stockholders' equity | 876,947 | 459,600 |
| Total liabilities and stockholders' equity | $ 897,225 | $ 476,168 |