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): May 14, 2024

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 May 14, 2024, Enliven Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. 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 May 14, 2024
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: May 14, 2024

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

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

Announced positive proof of concept data from Phase 1 clinical trial of ELVN-001 in CML, achieving an initial cumulative MMR rate of 44% (7/16) by 12 weeks in response-evaluable patients

Strong balance sheet with $321 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into late 2026

BOULDER, Colo., May 14, 2024 (GLOBE NEWSWIRE) – Enliven Therapeutics, Inc. (Enliven or the Company) (Nasdaq: ELVN), a clinical-stage precision oncology company focused on the discovery and development of next-generation small molecule kinase inhibitors, today reported financial results for the first quarter ended March 31, 2024, and provided a business update, including highlights of pipeline progress.

"The first quarter of 2024 was a pivotal quarter for Enliven. We released positive proof of concept data from our Phase 1 clinical trial of ELVN-001, which was a significant milestone for the Company" said Sam Kintz, MBA, Enliven's Co-founder and Chief Executive Officer. "We are thrilled by the initial ELVN-001 data, particularly the tolerability profile and evidence of activity in heavily pre-treated patients, including in patients with asciminib-resistant chronic myeloid leukemia. We also continued to advance our trials of ELVN-002, including the activation of the first site to evaluate ELVN-002 in combination with trastuzumab in patients with HER2+ cancers, which we believe is an area of significant unmet need for patients. Additionally, we extended our cash runway into late 2026 thanks to the support of new and existing investors."

Corporate Updates

- Entered into a securities purchase agreement for a private investment in public equity (PIPE) financing resulting in gross proceeds of $90 million. The financing, from both new and existing investors, is expected to extend the Company's cash runway into late 2026 and through multiple key milestones for ELVN-001 and ELVN-002.
- Appointed to the Board of Directors, Lori Kunkel, MD, an accomplished industry executive and board member with a track record of success in corporate strategy, clinical development and commercialization.

Pipeline Updates

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 chronic myeloid leukemia (CML).

- Announced positive proof of concept data from the Phase 1 clinical trial evaluating ELVN-001 in patients with CML who are relapsed, refractory or intolerant to available tyrosine kinase inhibitors (TKIs).

- As of the cutoff date of March 18, 2024, 44% (7/16) of response-evaluable patients achieved a cumulative major molecular response (MMR) rate by week 12, and patients with prior exposure to asciminib and/or who were TKI-resistant also demonstrated responses, with a 44% and 40% cumulative MMR rate, respectively. Among response-evaluable patients, all had improved or stable BCR::ABL1 transcript levels by 12 weeks. ELVN-001 was well tolerated with no Grade 3 or higher non-hematologic treatment-related adverse events and no dose reductions reported.
- These data compare favorably to precedent Phase 1 cumulative MMR rates for approved BCR::ABL1 TKIs, particularly given the more heavily pre-treated patient population. Further details can be found here.
- Phase 1b data is expected in 2025 and is expected to include between approximately 60-100 patients across various lines of therapy with significant follow-up.

ELVN-002 is a potent, highly selective, central nervous system penetrant and irreversible HER2 inhibitor with activity against wild type HER2 and various HER2 mutations.

- Following U.S. Food and Drug Administration approval of its Investigational New Drug application, the Company activated the first site to evaluate ELVN-002 in combination with trastuzumab +/- chemotherapeutic agents in HER2+ metastatic breast cancer (MBC) and colorectal cancer (CRC). First patient dosing for the combination trial is expected in Q2 2024.
- The combination trial in patients with HER2+ cancers is supported by the initial data from the ongoing monotherapy trial, which includes:
  - Investigator reported responses (including unconfirmed) in both HER2+ and HER2 mutant tumors, including in patients who have progressed on Enhertu and patients with brain metastases, at doses that have been well tolerated.
  - Importantly, at the clinically predicted optimal monotherapy dose, ELVN-002 had >10x target coverage based on pharmacokinetics in cancer patients and preclinical HER2+ efficacy compared to tucatinib.
- Phase 1 monotherapy data, Phase 1a/b Herceptin combination data in HER2+ CRC, and initial Phase 1a combination data in HER2+ MBC are expected in 2025.

First Quarter 2024 Financial Results

- **Cash Position:** As of March 31, 2024, the Company had cash, cash equivalents and marketable securities totaling $320.5 million, which is expected to provide cash runway into late 2026.
- **Research and development (R&D) expenses:** R&D expenses were $20.0 million for the first quarter of 2024, compared to $11.9 million for the first quarter of 2023.
- **General and administrative (G&A) expenses:** G&A expenses for the first quarter of 2024 were $6.0 million, compared to $4.5 million for the first quarter of 2023.
- **Net Loss:** Enliven reported a net loss of $22.7 million for the first quarter of 2024, compared to a net loss of $14.7 million for the first quarter of 2023.

About Enliven Therapeutics

Enliven Therapeutics is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule inhibitors to help people with cancer 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. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or 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 and expectations regarding Enliven's programs, including ELVN-001 and ELVN-002; Enliven's pipeline of product candidates; expected milestones for ELVN-001 and ELVN-002, including the expected timing of dosing of ELVN-002 for the combination trial and of data from the clinical trials of ELVN-001 and ELVN-002; statements relating to Enliven's expected cash runway; and the anticipated use of proceeds from the PIPE financing; 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 preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, 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; 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 contract manufacturing organizations, contract research organizations and strategic partners; 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.

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 March 31,**	
	2024	**2023**
Operating expenses:		
Research and development	$ 19,970	$ 11,880
General and administrative	6,017	4,538
Total operating expenses	25,987	16,418
Loss from operations	(25,987)	(16,418)
Other income (expense), net	3,249	1,694
Net loss	$ (22,738)	$ (14,724)
Net loss per share, basic and diluted	$ (0.54)	$ (0.80)
Weighted-average shares outstanding, basic and diluted	42,046	18,515

Balance Sheets	**March 31, 2024**	**December 31, 2023**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 320,504	$ 253,148
Restricted cash	54	54
Prepaid expenses and other current assets	6,641	2,949
Contingent value right asset	10,000	10,000
Total current assets	337,199	266,151
Property and equipment, net	683	742
Operating lease right-of-use assets	241	320
Deferred offering costs	563	563
Other long-term assets	4,091	4,091
Total assets	$ 342,777	$ 271,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,727	$ 532
Accrued expenses and other current liabilities	12,304	15,362
Contingent value right liability	10,000	10,000
Total current liabilities	25,031	25,894
Long-term liabilities	34	67
Total liabilities	25,065	25,961
Stockholders' equity	317,712	245,906
Total liabilities and stockholders' equity	$ 342,777	$ 271,867