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, 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 August 13, 2024, Enliven Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 13, 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: August 13, 2024

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

Dosed the first patient in the Phase 1b arm of the clinical trial evaluating ELVN-001 in patients with CML that is relapsed, refractory or intolerant to available TKIs

Dosed the first patient in the Phase 1a clinical trial evaluating ELVN-002 in combination with trastuzumab +/- chemotherapeutic agents in HER2+ MBC and CRC

Strong balance sheet with $312 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into late 2026

BOULDER, Colo., Aug. 13, 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 second quarter ended June 30, 2024, and provided a business update, including highlights of pipeline progress.

"The second quarter of 2024 marked another period of significant progress for both of our parallel lead programs, ELVN-001 and ELVN-002," said Sam Kintz, MBA, Enliven's Co-founder and Chief Executive Officer. "We began dosing patients in the Phase 1b arm for ELVN-001 and in two combination trials for ELVN-002. Additionally, an abstract updating the data from the ongoing Phase 1a trial for ELVN-001 has been accepted for presentation at the upcoming ESH-iCMLf Conference in September."

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).

- The first patient was dosed in the Phase 1b arm of the clinical trial evaluating ELVN-001 in patients with CML that is relapsed, refractory or intolerant to available tyrosine kinase inhibitors (TKIs).
- The Company announced positive proof of concept data from the Phase 1a clinical trial in April of this year, and an abstract with updated Phase 1a data was accepted for presentation at the European Society of Hematology International CML Foundation 26th Annual John Goldman Conference on CML taking place September 27-29 in Prague, Czech Republic.
- Additional Phase 1 data is expected in 2025 and is planned to include 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.

- The first patient was dosed in the Phase 1a trial evaluating ELVN-002 in combination with trastuzumab +/- chemotherapeutic agents in patients with HER2+ metastatic breast cancer (MBC) and colorectal cancer (CRC).
- Additionally, the first patient with HER2+ MBC was dosed in the exploratory Phase 1a arm evaluating ELVN-002 in combination with ado-trastuzumab emtansine (Kadcyla®), an approved HER2 antibody drug conjugate.
- Phase 1 monotherapy data and initial Phase 1a combination data are expected in 2025.

Second Quarter 2024 Financial Results

- **Cash Position:** As of June 30, 2024, the Company had cash, cash equivalents and marketable securities totaling $312.4 million, which is expected to provide cash runway into late 2026. The cash balance includes $10 million that was received from Cardurion for the achievement of a milestone pursuant to an asset purchase agreement entered into prior to the merger between Imara Inc. and Enliven Inc. In August 2024, Enliven remitted the milestone payment, less permitted deductions, to the stockholders of Enliven (formerly Imara) prior to the merger.
- **Research and development (R&D) expenses:** R&D expenses were $18.8 million for the second quarter of 2024, compared to $15.2 million for the second quarter of 2023.
- **General and administrative (G&A) expenses:** G&A expenses were $5.8 million for the second quarter of 2024, compared to $5.0 million for the second quarter of 2023.
- **Net Loss:** Net loss was $20.0 million for the second quarter of 2024, compared to $16.7 million for the second 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 data from the clinical trials of ELVN-001 and ELVN-002 and the number of patients included in such data; statements relating to 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 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.

Contact
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Media
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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,**	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 18,826	$ 15,183	$ 38,796	$ 27,063
General and administrative	5,777	4,951	11,794	9,489
Total operating expenses	24,603	20,134	50,590	36,552
Loss from operations	(24,603)	(20,134)	(50,590)	(36,552)
Other income (expense), net	4,653	3,413	7,902	5,107
Net loss	$ (19,950)	$ (16,721)	$ (42,688)	$ (31,445)
Net loss per share, basic and diluted	$ (0.41)	$ (0.41)	$ (0.95)	$ (1.05)
Weighted-average shares outstanding, basic and diluted	48,075	40,961	45,060	29,862

Balance Sheets	**June 30, 2024**	**December 31, 2023**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 312,390	$ 253,148
Restricted cash	54	54
Prepaid expenses and other current assets	5,683	2,949
Contingent value right asset	—	10,000
Total current assets	318,127	266,151
Property and equipment, net	630	742
Operating lease right-of-use assets	161	320
Deferred offering costs	563	563
Other long-term assets	7,562	4,091
Total assets	$ 327,043	$ 271,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,083	$ 532
Accrued expenses and other current liabilities	11,822	15,362
Contingent value right liability	9,200	10,000
Total current liabilities	22,105	25,894
Long-term liabilities	6	67
Total liabilities	22,111	25,961
Stockholders' equity	304,932	245,906
Total liabilities and stockholders' equity	$ 327,043	$ 271,867