

**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 11, 2023**

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.)

6200 Lookout Road
Boulder, CO
(Address of principal executive offices)

80301
(Zip Code)

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

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 Conditions.

On May 11, 2023, Enliven Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2023. 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 11, 2023
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 11, 2023

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



Enliven Therapeutics Highlights Business Achievements and Reports First Quarter 2023 Financial Results

Successfully completed merger with Imara Inc., trading under the new ticker symbol on Nasdaq, "ELVN"

Dosed first patient in Phase 1 study of ELVN-002 in patients with HER2-altered non-small cell lung cancer (NSCLC) and other solid tumors

Enrollment progressing in Phase 1 trial with ELVN-001 in chronic myeloid leukemia (CML)

Ended the first quarter 2023 with cash and cash equivalents of approximately \$292 million, which is expected to provide cash runway into early 2026

BOULDER, Colo., May 11, 2023 (GLOBE NEWSWIRE) — Enliven Therapeutics, Inc. (Enliven) (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, 2023 and provided a business update.

"2023 is off to a strong start with the successful completion of our merger with Imara Inc. and the concurrent private financing, dosing of the first patient in the Phase 1 study of ELVN-002, continued progression of enrollment in our Phase 1 trial for ELVN-001, and good progress on our discovery pipeline," said Sam Kintz, MBA, Enliven's Co-founder and President and Chief Executive Officer. "2023 is a critical year of execution for us as our parallel lead programs advance ahead of expected Phase 1a data for both programs in 2024."

Recent Business Highlights and Upcoming Milestones

Research and Development Highlights

- **ELVN-002:** Dosed the first patient in the Phase 1 clinical trial evaluating ELVN-002 in people with cancers harboring an abnormal HER2 gene ([NCT05650879](#)). ELVN-002 is a CNS penetrant, selective and irreversible HER2 inhibitor with activity against various HER2 mutations, including Exon 20 insertion mutations (E20IMs) in NSCLC, for which there are currently no approved small molecule inhibitors. The Company expects to share initial safety and efficacy data from the Phase 1a study in 2024.
- **ELVN-001:** Continued progress in the dose escalation portion of the Phase 1 clinical trial evaluating ELVN-001 in adults with CML ([NCT05304377](#)). The Company expects to share initial safety and efficacy data from the Phase 1a study in 2024.
- **Pipeline:** Progress toward nominating a product candidate for a third program, which is expected in the second quarter of this year. Enliven is also actively pursuing multiple additional early-stage discovery programs.

- In February 2023, Enliven successfully completed the merger with Imara Inc. and concurrent private financing, and the combined company's shares commenced trading under the new ticker "ELVN" on February 24, 2023. The Company's cash and cash equivalents, including proceeds from the merger and the concurrent private financing, are expected to fund the Company's planned operations into early 2026.

First Quarter 2023 Financial Results

- **Cash Position:** As of March 31, 2023, the Company had cash and cash equivalents totaling \$292.1 million.
- **Research and development (R&D) expenses:** R&D expenses were \$11.9 million for the first quarter of 2023, compared to \$7.1 million for the first quarter of 2022.
- **General and administrative (G&A) expenses:** G&A expenses for the first quarter of 2023 were \$4.5 million, compared to \$1.6 million for the first quarter of 2022.
- **Net Loss:** Enliven reported a net loss of \$14.7 million for the first quarter of 2023, compared to a net loss of \$8.7 million for the first quarter of 2022.

About Enliven Therapeutics

Enliven Therapeutics is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule inhibitors to help patients with cancer not only live longer, but better. Enliven aims to address existing and emerging unmet needs with a precision oncology approach that improves survival and enhances overall patient 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 (Securities Act)) 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, ELVN-002 and its early-stage discovery programs; the expected timing of Phase 1a data for ELVN-001 and ELVN-002 and timing for making a product candidate nomination for Enliven's third program; expectations regarding the sufficiency of Enliven's capital resources and cash runway; and statements by Enliven's Co-founder, President 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 factors, including, without limitation: the limited operating history of Enliven; the significant net losses incurred since its inception; 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 for the results of clinical trials to differ from preclinical, preliminary, initial or expected results; the risk of significant adverse events, toxicities or other undesirable side effects; Enliven's limited resources; Enliven's ability to obtain additional capital to finance its operations; the decision to develop or seek strategic collaborations to develop Enliven's current or future product candidates in combination with other therapies; Enliven's lack of experience in commercializing a product candidate; the ability to attract, hire, and retain 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; developments relating to Enliven's competitors and its industry, including competing product candidates and therapies; reliance on third parties, including contract manufacturing organizations, and contract research organizations; general economic and market conditions; and other risks and uncertainties, including those more fully described in Enliven's filings with the Securities and Exchange Commission (SEC), including Enliven's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2023 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.

Contact:

Enliven Investors & Media:

Argot Partners

Enliven@argotpartners.com

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

Statements of Operations	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 11,880	\$ 7,059
General and administrative	4,538	1,619
Total operating expenses	<u>16,418</u>	<u>8,678</u>
Loss from operations	(16,418)	(8,678)
Other income (expense), net	1,694	9
Net loss	<u>\$ (14,724)</u>	<u>\$ (8,669)</u>
Net loss per share, basic and diluted	\$ (0.80)	\$ (3.01)
Weighted-average shares outstanding, basic and diluted	18,515	2,877
Balance Sheets	March 31,	December 31,
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 292,102	\$ 75,536
Prepaid expenses and other current assets	5,901	2,217
Total current assets	<u>298,003</u>	<u>77,753</u>
Property and equipment, net	853	890
Right-of-use asset	551	626
Deferred offering costs	—	3,975
Restricted cash	54	54
Other long-term assets	3,405	—
Total assets	<u>\$ 302,866</u>	<u>\$ 83,298</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 5,860	\$ 3,438
Accrued expenses and other current liabilities	5,082	6,277
Total current liabilities	<u>10,942</u>	<u>9,715</u>
Long-term liabilities	508	659
Total liabilities	<u>11,450</u>	<u>10,374</u>
Convertible preferred stock	—	149,749
Stockholders' equity (deficit)	291,416	(76,825)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 302,866</u>	<u>\$ 83,298</u>