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 9, 2023

IKENA ONCOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40287**	**81-1697316**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Ikena Oncology, Inc.
645 Summer Street, Suite 101
Boston, Massachusetts 02210
(Address of principal executive offices, including zip code)

(857) 273-8343
(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:

☐ 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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**IKNA**	**The Nasdaq Global 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 9, 2023, Ikena Oncology, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to this Item 2.02 (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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On November 9, 2023, the Company shared initial data from twenty-six (26) patients treated in the ongoing dose escalation portion of the Phase I clinical trial of IK-930, a novel, oral, potent, and highly selective Hippo pathway inhibitor.

IK-930 Dose Escalation Summary and Differentiated Safety Profile

- 26 patients have been treated with IK-930 in dose escalation as of October 31, 2023
- IK-930 is in the final stages of dose optimization; the tolerability profile observed thus far supports the hypothesis that IK-930's selectivity could provide a wider therapeutic index for this new class of compounds
    - Proteinuria is an adverse effect of special interest as it may be an on-target effect of broad TEAD inhibition
    - Treatment-related proteinuria was recorded in 3 out of 26 dose escalation patients and was limited to grade 1-2
        - The observed proteinuria did not result in dose reduction or treatment interruption; no proteinuria events were considered dose-limiting and in all cases was fully reversible
    - Other safety observations include:
        - Frequent adverse events to date have been low-grade nausea, fatigue, and diarrhea, and have not required any dose reduction
        - Two epithelioid hemangioendothelioma ("EHE") patients with significant liver metastases experienced reversible liver enzyme elevation
            - One of these patients developed treatment-related grade 3 elevation, deemed dose limiting (the only dose limiting toxicity observed), and the patient remains on study after dose adjustment
            - The other patient experienced grade 3-4 elevation that was deemed possibly treatment related;
        - Dose escalation is currently ongoing
    - 15 patients were treated with doses within the projected efficacious exposure range and pharmacokinetic data showed some variability
        - 7 out of 15 patients were determined to reach efficacious exposure

- Target engagement in tumor, as determined by decreased TEAD gene signature, has been demonstrated in the efficacious dose range
- To minimize IK-930 exposure variability, a next generation formulation is now being evaluated in the dose escalation
- Recommended dosing for the next stage of the IK-930 program is expected to be determined in the near-term

Emerging Proof of Concept in EHE

- Seven patients with EHE have been treated with IK-930 in the dose escalation portion of the trial
  - 7 out of 7 EHE patients reached stable disease as a best response so far as measured by RECIST
  - 3 out of the 7 patients experienced tumor shrinkage in multiple target and non-target lesions
  - 4 out of 7 highly symptomatic EHE patients enrolled across multiple dose levels reported symptomatic improvement and subjective improvement of quality of life such as improved energy, weight gain, and pain control
  - 3 out of the 7 patients continue on treatment with time on treatment ranging from 18 to 26 weeks and ongoing
- As a result of these initial tolerability and antitumor activity findings, enrollment in the dose escalation phase continues to progress in targeted populations, including mesothelioma and meningioma, in addition to EHE
- Based on preclinical data indicating IK-930 synergy with EGFR inhibitors to combat therapeutic resistance, a combination cohort for IK-930 and osimertinib in patients with EGFR-mutant non-small cell lung cancer (NSCLC) is planned to initiate in 2024
- An additional data update from the IK-930 clinical program is planned for the second half of 2024

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Ikena Oncology, Inc. Press Release, dated November 9, 2023
104	Cover Page Interactive Data File

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Ikena Oncology, Inc.

Date: November 9, 2023

By: /s/ Mark Manfredi
Mark Manfredi, Ph.D.
President and Chief Executive Officer

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EXHIBIT 99.1

Ikena Oncology Shares Initial Positive and Differentiated Dose Escalation Data from IK-930 Phase I Trial and Reports Third Quarter 2023 Financial Results

Favorable safety profile in dose escalation shown to date; selective TEAD1 inhibition with IK-930 resulted in minimal treatment-related proteinuria without any dose reductions or treatment interruptions

Encouraging signs of clinical activity and tumor shrinkage in multiple patients with difficult-to-treat epithelioid hemangioendothelioma (EHE) during dose escalation

Additional IK-930 clinical data update planned for the second half of 2024; increased focus on enrollment of targeted populations including patients with mesothelioma and other NF2 mutant solid tumors

Pipeline build continues with clinical startup for IK-595, a MEK-RAF molecular glue, anticipated by end of 2023; Cash runway into 2026

BOSTON, November 9, 2023, –Ikena Oncology, Inc. (Nasdaq: IKNA, "Ikena," "Company"), a targeted oncology company forging new territory in patient-directed cancer treatment, today announced financial results for the quarter ended September 30, 2023, and provided a corporate update. The Company also shared initial data from twenty-six (26) patients treated in the ongoing dose escalation portion of the Phase I clinical trial of IK-930, a novel, oral, potent, and highly selective Hippo pathway inhibitor.

"This early look at the IK-930 dose escalation data strongly supports our differentiated approach to targeting the Hippo pathway. Importantly, following the target biology and initially focusing on EHE has allowed us to observe clinical activity of IK-930 early in our dose escalation. Even in the projected efficacious exposure range and at doses with clinical activity, IK-930 has thus far circumvented the renal toxicity observed with pan-TEAD inhibitors," commented Mark Manfredi, Ph.D., Chief Executive Officer of Ikena. "Now, with IK-930's safety profile allowing us to potentially dose patients to their optimal benefit, combined with sufficient capital to drive us through multiple data readouts, we are looking ahead to a series of rapid next steps with the program. We are increasing our focus on our targeted monotherapy indications, such as EHE and mesothelioma, and have growing confidence that as we continue the program IK-930 may be able provide the therapeutic window and clinical benefit these patient populations need."

IK-930 Dose Escalation Summary and Emerging Proof of Concept in EHE

IK-930 selectively binds TEAD1 and broadly represses oncogenic TEAD signaling as a potent Hippo-pathway inhibitor, a known suppressor pathway in cancers such as epithelioid hemangioendothelioma (EHE), mesothelioma, meningioma, and others. IK-930's differentiated paralog selectivity and robust repressor activity in complex with VGLL4 are key characteristics supporting anti-tumor effect in preclinical models. IK-930 is designed to circumvent renal toxicity, potentially resulting in an optimized therapeutic index. Twenty-six patients with a range of solid tumors were treated in the dose escalation portion of the study as of October 31, 2023. The most common tumor type enrolled was EHE.

Differentiated Safety Profile

- 26 patients have been treated with IK-930 in dose escalation as of October 31, 2023
- IK-930 is in the final stages of dose optimization; the tolerability profile observed thus far supports the hypothesis that IK-930's selectivity could provide a wider therapeutic index for this new class of compounds
    - Proteinuria is an adverse effect of special interest as it may be an on-target effect of broad TEAD inhibition
    - Treatment-related proteinuria was recorded in 3 out of 26 dose escalation patients and was limited to grade 1-2
        - The observed proteinuria did not result in dose reduction or treatment interruption; no proteinuria events were considered dose-limiting and in all cases was fully reversible
    - Other safety observations include:
        - Frequent adverse events to date have been low-grade nausea, fatigue, and diarrhea, and have not required any dose reduction
        - Two EHE patients with significant liver metastases experienced reversible liver enzyme elevation
            - One of these patients developed treatment-related grade 3 elevation, deemed dose limiting (the only DLT observed), and the patient remains on study after dose adjustment
            - The other patient experienced grade 3-4 elevation that was deemed possibly treatment related;
        - Dose escalation is currently ongoing
    - 15 patients were treated with doses within the projected efficacious exposure range and pharmacokinetic data showed some variability
        - 7 out of 15 patients were determined to reach efficacious exposure
        - Target engagement in tumor, as determined by decreased TEAD gene signature, has been demonstrated in the efficacious dose range
        - To minimize IK-930 exposure variability, a next generation formulation is now being evaluated in the dose escalation
        - Recommended dosing for the next stage of the IK-930 program is expected to be determined in the near-term

Emerging Proof of Concept in EHE

Epithelioid hemangioendothelioma is a rare vascular sarcoma defined by gene fusions of either YAP or TAZ genes in the Hippo pathway with other transcriptional regulators. EHE is a slow-growing, invasive tumor with no approved treatment options and is challenging to measure due to diffuse infiltration of multiple organs. It can occur in multiple areas of the body, including the liver, lungs, bones, and blood vessels. People with EHE suffer symptoms that relentlessly affect their quality of life and are consistent with the site of the EHE growth, including liver failure, respiratory issues, and gastrointestinal symptoms, which are frequently accompanied by severe pain across the body. With no approved standard of care, there is substantial need for innovative treatments that can provide clinical benefit and symptom relief and slow or limit the progression of disease.

- Seven patients with EHE have been treated with IK-930 in the dose escalation portion of the trial
    - 7 out of 7 EHE patients reached stable disease as a best response so far as measured by RECIST
    - 3 out of the 7 patients experienced tumor shrinkage in multiple target and non-target lesions
    - 4 out of 7 highly symptomatic EHE patients enrolled across multiple dose levels reported symptomatic improvement and subjective improvement of quality of life such as improved energy, weight gain, and pain control
    - 3 out of the 7 patients continue on treatment with time on treatment ranging from 18 to 26 weeks and ongoing
- As a result of these initial tolerability and antitumor activity findings, enrollment in the dose escalation phase continues to progress in targeted populations including mesothelioma and meningioma, in addition to EHE
- Based on preclinical data indicating IK-930 synergy with EGFR inhibitors to combat therapeutic resistance, a combination cohort for IK-930 and osimertinib in patients with EGFR-mutant non-small cell lung cancer (NSCLC) is planned to initiate in 2024
- An additional data update from the IK-930 clinical program is planned for the second half of 2024

“EHE is a rare soft tissue sarcoma for which there is no known treatment. This tumor is 100% driven by the Hippo pathway which has motivated our initial development of IK-930 in EHE, despite the challenge of assessing the disease burden and treatment effects. The EHE patient community is one of the strongest I have worked with. The physicians, patients, and supportive community are deeply committed to finding innovative solutions in EHE, and we are immensely grateful for their partnership in these early days of the IK-930 clinical program,” commented Sergio Santillana, M.D., Chief Medical Officer of Ikena.

“The EHE community is excited by this early data from IK-930, the first targeted agent for patients with EHE, and we eagerly await more data. Rare cancers, like EHE, present significant challenges for drug developers, and we are encouraged by Ikena’s commitment to this program. We are grateful for the participation of EHE patients, caregivers, and physicians in the trial, and we look forward to continuing our partnership with Ikena,” commented Tammy Silverthorne, Executive Director of The EHE Foundation.

Summary of Additional Recent Pipeline Progress and Corporate Updates

IK-595: MEK-RAF Molecular Glue

- IK-595 clinical trial anticipated to initiate by year end 2023
- Additional preclinical updates were presented at the 5th Annual RAS-Targeted Drug Development Conference in September and AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October

IK-175: AHR Inhibitor in Collaboration with Bristol Myers Squibb

- The Phase 1 clinical trial in urothelial carcinoma has completed enrollment and the program is eligible for opt-in from Bristol Myers Squibb through early 2024

Corporate Updates

- In August 2023, the Company acquired Pionyr Immunotherapeutics, Inc. (“Pionyr”), a privately held biotech company, in an all-stock transaction
    - Ikena acquired all of Pionyr assets, including approximately $43 million in net cash in exchange for shares of Ikena stock at price of $7.15 per share
    - The valuation for the transaction was determined solely by net cash available at closing
- The Company believes that cash at hand will be sufficient to meet its operating requirements into 2026 through multiple data events for both IK-930 and IK-595

Financial Results for the Quarter Ended September 30, 2023

As of September 30, 2023, Ikena had $196.9 million in cash, cash equivalents and marketable securities. Net cash used in operating activities was $19.9 million for the three months ended September 30, 2023, as compared to $17.2 million of cash used in operating activities for the same period in 2022.

Collaboration revenue was $1.2 million and $6.4 million for the three months ended September 30, 2023 and 2022, respectively. The decrease in revenue of $5.2 million was primarily due to an increase in manufacturing activities as a result of the substantial completion of manufacturing efforts related to the IK-412 program during the three months ended September 30, 2022.

Research and development expenses were $14.7 million and $18.9 million for the three months ended September 30, 2023 and 2022, respectively. The decrease in research and development expenses of $4.2 million was primarily due to decreases in clinical trial costs related to IK-175 and decreases in other discovery stage programs as a result of the Company prioritizing its focus on advancing its clinical stage programs, partially offset by costs incurred to wind down Pionyr clinical trials.

General and administrative expenses were $6.0 million and $5.4 million for the three months ended September 30, 2023 and 2022, respectively. The increase in general and administrative expenses of $0.6 million was primarily attributable to an increase in legal expenses.

About Ikena Oncology

Ikena Oncology® is focused on developing differentiated therapies for patients in need that target nodes of cancer growth, spread, and therapeutic resistance in the Hippo and RAS onco-signaling network. The Company's lead targeted oncology program, IK-930, is a TEAD1 selective Hippo pathway inhibitor, a known tumor suppressor pathway that also drives resistance to multiple targeted therapies. The Company's additional research spans other targets in the Hippo pathway as well as the RAS signaling pathway, including developing IK-595, a novel MEK-RAF inhibitor. Additionally, IK-175, an AHR antagonist, is being developed in collaboration with Bristol Myers Squibb. Ikena aims to utilize their depth of institutional knowledge and breadth of tools to efficiently develop the right drug using the right modality for the right patient. To learn more, visit www.ikenaoncology.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding: the timing and advancement of our targeted oncology programs, including the timing of updates; our expectations regarding the therapeutic benefit of our targeted oncology programs; our ability to efficiently discover and develop product candidates; our ability to obtain and maintain regulatory approval of our product candidates; expectations with respect to projected cash runway; the anticipated use of proceeds from the Pionyr acquisition; the implementation of our business model; and strategic plans for our business and product candidates. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements

contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of our targeted oncology programs; our expectations regarding the therapeutic benefit of our targeted oncology programs; our ability to efficiently discover and develop product candidates; the implementation of our business model, and strategic plans for our business and product candidates, the sufficiency of the Company's capital resources to fund operating expenses and capital expenditure requirements and the period in which such resources are expected to be available, and other factors discussed in the "Risk Factors" section of Ikena's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, which is on file with the SEC, as updated by any subsequent SEC filings. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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Financial Tables

Selected Balance Sheet Items

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 121,277	$ 59,919
Marketable securities	$ 75,656	$ 97,028
Total assets	$ 215,335	$ 172,259
Total liabilities	$ 28,146	$ 25,290
Convertible Preferred Stock	$ 31,845	$ -
Additional paid-in-capital	$ 418,486	$ 361,915
Accumulated deficit	$ (262,896)	$ (214,219)
Total stockholders' equity	$ 155,344	$ 146,969

Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development revenue under collaboration agreement	$ 1,185	$ 6,402	$ 8,501	$ 10,168
Operating expenses:				
Research and development	14,654	18,850	45,378	48,682
General and administrative	6,034	5,428	16,632	17,276
Total operating expenses	20,688	24,278	62,010	65,958
Loss from operations	(19,503)	(17,876)	(53,509)	(55,790)
Investment income	2,162	550	4,840	1,135
Other expense	(2)	(12)	(8)	(13)
Total other income, net	2,160	538	4,832	1,122
Net loss	$ (17,343)	$ (17,338)	$ (48,677)	$ (54,668)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	166	(77)	(290)	(1,181)
Total comprehensive loss	$ (17,177)	$ (17,415)	$ (48,967)	$ (55,849)
Net loss per share:				
Net loss per share attributable to common stockholders basic and diluted	$ (0.40)	$ (0.48)	$ (1.23)	$ (1.51)
Weighted-average common stocks outstanding, basic and diluted	43,437,844	36,257,074	39,688,984	36,165,143