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 10, 2022

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 7.01 Regulation FD Disclosure.

On November 10, 2022, Ikena Oncology, Inc. (the "Company") issued a press release announcing initial clinical data from its ongoing IK-175 clinical program in urothelial carcinoma. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (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 filing.

Item 8.01 Other Items.

On November 10, 2022, the Company presented initial clinical data from its ongoing IK-175 clinical program in urothelial carcinoma at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting in Boston, MA.

Initial results demonstrate durable antitumor activity in heavily pretreated patients in both monotherapy and combination arms in urothelial carcinoma patients **who all progressed on prior checkpoint inhibitors**.

Key Data Highlights: IK-175 Dose Escalation, Stage 1 of Dose Expansion Monotherapy in Urothelial Carcinoma, and Stage 1 of Combination with Nivolumab Expansion in Urothelial Carcinoma

- **Durable antitumor activity across evaluable patients**
  - Initial analysis includes 43 patients treated across all arms
  - Dose expansion in urothelial carcinoma: 20 response evaluable patients (10 monotherapy, 10 combination)
    - Expansion cohorts each follow a Simon 2-stage design
    - Patients included in analysis from stage 1 of each expansion cohort; stage 2 of the cohorts continue to enroll
    - **IK-175 monotherapy**
      - **1 confirmed partial response with a duration of response (DoR) of 14.9 months and ongoing; 1 stable disease patient**
      - **10% overall response rate (ORR), 20% disease control rate (DCR)**
    - **IK-175 combination with nivolumab**
      - **2 confirmed partial responses with DoR 4.5-6 months and ongoing; 2 stable disease patients**
      - **Overall response rate 20% (ORR), disease control rate 40% (DCR)**
  - Dose escalation in all solid tumors; 20 evaluable patients (15 monotherapy, 5 combination)
    - All solid tumors enrolled, including non-small-cell lung cancer, ovarian, colon, appendiceal carcinoma, pancreatic carcinoma and others; included patients who received up to 10 lines of prior therapy
    - **In dose escalation 3/15 (monotherapy, 20% DCR) and 2/5 (combination, 40% DCR) patients had prolonged stable disease up to over 19 months**
- **IK-175 was well tolerated, with a predictable and manageable safety profile**
  - Maximum tolerated dose was not reached and no dose limiting toxicities were observed; 1200mg was selected as the expansion dose
  - Most frequently occurring treatment-related adverse events were low-grade rash and nausea (monotherapy) and low-grade fatigue and dysgeusia (combination); there were only 2 serious adverse events
  - Immune-related events were reported in both monotherapy and combination arms, supporting the immune-modulatory effect of IK-175

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Ikena Oncology, Inc. Press Release
104	Cover Page Interactive Data File

SIGNATURE

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.

Ikena Oncology, Inc.

Date: November 10, 2022

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

Ikena Oncology Announces Initial Clinical Data from IK-175 Program in Urothelial Carcinoma

IK-175 combined with nivolumab showed durable antitumor activity with a 20% ORR and 40% DCR in heavily pretreated urothelial carcinoma

IK-175 monotherapy activity observed; confirmed partial response with DoR of 14.9 months and ongoing

Program in collaboration with Bristol Myers Squibb and eligible for opt-in through early 2024

BOSTON, November 10, 2022 – Ikena Oncology, Inc. (Nasdaq: IKNA, "Ikena"), a targeted oncology company forging new territory in patient-directed cancer treatment, today presented initial clinical data from its ongoing IK-175 clinical program in urothelial carcinoma at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting in Boston, MA.

"We are glad to share the initial results from this study showing encouraging antitumor activity of IK-175 in urothelial carcinoma. These patients have exhausted all therapeutic options and progressed within 12 weeks of their last checkpoint treatment. It is an exciting development to observe IK-175 as well tolerated, achieving prolonged objective responses and disease control in this refractory patient population," said Sergio Santillana, MD, Chief Medical Officer of Ikena. "These initial data suggest we are making progress towards demonstrating that IK-175 in combination with nivolumab could overcome resistance to immune checkpoint inhibitors in urothelial carcinoma. Ultimately, we hope these data are a step towards IK-175 expanding the number of cancer patients who could benefit from immunotherapy."

Initial results demonstrate durable antitumor activity in heavily pretreated patients in both monotherapy and combination arms in urothelial carcinoma patients **who all progressed on prior checkpoint inhibitors.**

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- Dose escalation in all solid tumors; 20 evaluable patients (15 monotherapy, 5 combination)
    - All solid tumors enrolled, including non-small-cell lung cancer, ovarian, colon, appendiceal carcinoma, pancreatic carcinoma and others; included patients who received up to 10 lines of prior therapy
    - **In dose escalation 3/15 (monotherapy, 20% DCR) and 2/5 (combination, 40% DCR) patients had prolonged stable disease up to over 19 months**
- **IK-175 was well tolerated, with a predictable and manageable safety profile**
    - Maximum tolerated dose was not reached and no dose limiting toxicities were observed; 1200mg was selected as the expansion dose
    - Most frequently occurring treatment-related adverse events were low-grade rash and nausea (monotherapy) and low-grade fatigue and dysgeusia (combination); there were only 2 serious adverse events
    - Immune-related events were reported in both monotherapy and combination arms, supporting the immune-modulatory effect of IK-175

Dr. David Aggen, one of the lead investigators on the trial and author on the poster commented: “This bladder cancer patient population are often out of options, and it is extremely challenging to find therapies that can overcome their previous treatment failures. It is exciting to see this type of antitumor activity with IK-175-nivolumab combination therapy for these patients and I am looking forward to seeing how IK-175 advances the bladder cancer treatment paradigm.”

Presentation Details

- **Poster #**: 661
- **Title**: Initial results from a Phase 1a/b study of IK-175, an oral AHR inhibitor, as a single agent and in combination with nivolumab in patients with advanced solid tumors and urothelial carcinoma
- **Presenter**: David Aggen, M.D. Ph.D. (MSKCC)
- Available in the poster hall November 10, 2022, through the conference website, and on the company website

About IK-175-001

The study is an ongoing Phase 1b, open-label dose escalation and expansion study of IK-175 in those diagnosed with local or advanced solid tumors or unresectable urothelial carcinoma who have exhausted prior therapies and have seen disease progression on or within 12 weeks of the last dose of checkpoint inhibitor. IK-175 treats cancer through a novel mechanism, inhibiting the cancer-driving transcription factor known as the aryl hydrocarbon receptor (AHR) and modulating the tumor microenvironment. Through a body of translational data, including data generated with Ikena’s internally discovered biomarkers and novel assays, AHR has been demonstrated to be upregulated in urothelial carcinoma and other solid tumors leading to an increase in immunosuppressive effects and resistance to checkpoint inhibitor treatment. Responses are evaluated through RECIST 1.1. The expansion cohorts enrolled only urothelial carcinoma patients and are designed as Simon-2-stage cohorts. Both the monotherapy and combination arms advanced to stage 2 and enrollment is ongoing. Ikena’s IK-175 program is being developed in collaboration with Bristol Myers Squibb. Bristol Myers Squibb has an option to exclusively license the program through early 2024. The therapy is also being studied in a Phase 1, open-label, single-arm dose expansion study in combination with nivolumab in advanced head and neck cancer (IK-175-002).

About Ikena Oncology

Ikena Oncology™ is focused on developing novel therapies targeting key signaling pathways that drive the formation and spread of cancer. The Company's lead targeted oncology program, IK-930, is a paralog-selective TEAD inhibitor addressing the Hippo signaling pathway, a known tumor suppressor pathway that also drives resistance to multiple targeted therapies. The Company's ongoing discovery research spans other targets in the Hippo pathway as well as the RAS signaling pathway. Additional programs targeting the tumor microenvironment and immune signaling are in the clinic, including IK-175, an AHR antagonist, which is being developed in collaboration with Bristol Myers Squibb. Ikena's pipeline is built on addressing genetically defined or biomarker-driven cancers and developing therapies that can serve specific patient populations in need of new therapeutic options. 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, 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; 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; expectations regarding our new executive officer; our ability to efficiently discover and develop product candidates; the implementation of our business model, and strategic plans for our business and product candidates, and other factors discussed in the "Risk Factors" section of Ikena's Form 10-Q for the quarter ended September 30, 2022, 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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