

**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 13, 2021

IKENA ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40287
(Commission
File Number)

81-1697316
(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 May 13, 2021, Ikena Oncology, Inc. announced its financial results for the quarter ended March 31, 2021. 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 in this 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 a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release dated May 13, 2021.](#)

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: May 13, 2021

By: /s/ Mark Manfredi

Mark Manfredi, Ph.D.

President and Chief Executive Officer



Ikena Oncology Reports First Quarter 2021 Financial Results and Outlines Key Corporate Objectives for 2021

Closed IPO and Raised \$144 Million in Gross Proceeds to Fund Targeted Oncology Therapies

IND Submissions for Lead Targeted Oncology Program, IK-930, and BMS-partnered program, IK-412, Remain on Track for Second Half of 2021

Boston, MA – May 13, 2021 – Ikena Oncology, Inc. (Nasdaq: IKNA) (“Ikena”, “the Company”, “we”, “our”), a targeted oncology company focused on developing therapies targeting key signaling pathways that drive the formation and spread of cancer, today announced financial results for the quarter ended March 31, 2021.

“This first quarter marked important milestones for Ikena, both with our entrance into the public markets and the advances we have made across our pipeline. We continued to progress our clinical development programs and our lead targeted oncology program is on track for an IND submission in the second half of the year,” said Mark Manfredi, PhD, President & Chief Executive Officer of Ikena. “We are thrilled that through our IPO, we brought in new long-term partners and deepened our relationships with our current investors. The funding, along with a dedicated and passionate team, are propelling us towards our mission of bringing novel targeted cancer therapies to patients.”

Recent Business Highlights and Corporate Update

Financial and Corporate

- In March 2021, Ikena completed a successful initial public offering (IPO), raising \$143.8 million in aggregate gross proceeds, before deducting underwriting discounts and commissions and estimated offering expenses, and listed on The Nasdaq Global Market. The IPO followed the closing of a Series B crossover financing of \$120 million in gross proceeds in December 2020.
- In April 2021, Maria Koehler, MD, PhD, current Chief Medical Officer of Repare Therapeutics, Inc. (NASDAQ: RPTX), was appointed to the Ikena Board of Directors. Dr. Koehler is a board-certified hematologist and oncologist with more than 20 years of pharmaceutical and biotech oncology experience in clinical development, including senior roles at Pfizer where she contributed to the strategic direction of the oncology portfolio.

- **IK-930:** IND-enabling studies are ongoing for Ikena's lead targeted oncology program, IK-930, a potent, selective and well tolerated oral small molecule TEAD inhibitor in the Hippo signaling pathway. In preclinical studies, IK-930 demonstrated anti-tumor activity in Hippo pathway-driven cancer models and synergy with EGFR inhibition and MEK inhibition.
- **ERK5 Inhibitor:** Lead optimization is ongoing for Ikena's ERK5 inhibitor program which is being developed for the treatment of KRAS mutant tumors. Ikena's ERK5 tool molecule inhibitor has shown single agent and synergistic anti-tumor activity with MEK inhibition in preclinical models of KRAS mutant pancreatic cancer and lung adenocarcinoma.
- **IK-175:** The ongoing Phase 1b clinical trial with IK-175, Ikena's AHR antagonist, continues to enroll patients in the monotherapy dose expansion arm. In addition, the first patient was recently dosed in the dose escalation combination arm which consists of IK-175 with nivolumab in patients with bladder cancer, including patients with AHR-activated tumors.
- **IK-412:** IND-enabling studies are currently ongoing for IK-412, a novel enzymatic therapeutic designed to lower levels of kynurenine, an immunosuppressive metabolite in the tumor microenvironment. IK-412 has demonstrated profound and durable kynurenine depletion in preclinical models.
- **IK-007:** The ongoing Phase 1b clinical trial continues to enroll patients with advanced or progressive microsatellite stable colorectal cancer (MSS-CRC) with IK-007 in combination with pembrolizumab. The clinical trial is enriching for patients that have high urinary prostaglandin E metabolite (PGEM) biomarker.

Milestones and Key Priorities for 2021

- Complete IND-enabling studies for TEAD inhibitor, IK-930, and submit IND application to FDA during the second half of 2021.
- Nominate ERK5 inhibitor development candidate and initiate IND-enabling studies in the second half of 2021.
- Complete IND-enabling studies for kynurenine degrading enzyme, IK-412, and submit IND to FDA during the second half of 2021.
- Complete enrollment into the Phase 1b study of EP4 antagonist IK-007 in combination with pembrolizumab in patients with advanced or progressive MSS-CRC.

First Quarter 2021 Financial Results

As of March 31, 2021, the Company had cash and cash equivalents totaling \$281.0 million, which will fund operations through 2023. Net cash used in operations was \$13.2 million for the first quarter of 2021 compared to \$9.9 million for the first quarter of 2020.

Research and development expenses for the first quarter 2021 were \$10.0 million, compared to \$7.9 million for the first quarter 2020. The increase in R&D expense was primarily related to on-going IND-enabling studies and manufacturing development costs for IK-930, on-going IND-enabling studies and manufacturing development costs for IK-142, increased research activities of other discovery stage programs and increased personnel expenses due to increase in headcount.

General and administrative expenses for the first quarter were \$3.2 million, compared to \$2.5 million for the first quarter 2020. The increase in G&A expense were primarily related to compensation expense due to an increase in headcount, as well as general increases in audit, legal and consulting expenses to support our transition to becoming a public company.

Net loss for the first quarter 2021 was \$9.7 million, compared to \$6.9 million for the first quarter 2020, driven predominantly by increase in research and development expenses.

About Ikena Oncology

Ikena Oncology is a targeted oncology company focused on developing cancer therapies targeting key signaling pathways that drive the formation and spread of cancer. Ikena is advancing five programs that include four product candidates in either clinical development or IND-enabling studies: IK-930, a TEAD inhibitor targeting the Hippo signaling pathway; an ERK5 inhibitor program targeting the KRAS signaling pathway; IK-175, an AHR antagonist; IK-412, a kynurenine-degrading enzyme; and IK-007, an EP4 receptor antagonist. Ikena has entered into a global strategic collaboration with Bristol-Myers Squibb Company for its IK-175 and IK-412 programs. 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; our expectations regarding the therapeutic benefit of our targeted oncology programs; expectations regarding our new director; 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 director; 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, and other risks identified in our SEC filings, including our Registration Statement on Form S-1, and subsequent filings with the SEC. 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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**Condensed Consolidated Balance Sheet Data
(Unaudited)
(in thousands)**

| | March 31, 2021 | December 31, 2020 |
|--|---------------------------|------------------------------|
| Cash and cash equivalents | \$ 281,010 | \$ 162,491 |
| Total assets | 293,662 | 168,404 |
| Total liabilities | 66,018 | 63,473 |
| Redeemable convertible preferred stock | — | 205,979 |
| Additional paid-in-capital | 348,663 | 10,288 |
| Accumulated deficit | (121,055) | (111,339) |
| Total stockholders' equity (deficit) | 227,644 | (101,048) |

Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands)

| | <u>Three Months Ended March 31,</u> | |
|--|-------------------------------------|-------------------|
| | <u>2021</u> | <u>2020</u> |
| Research and development revenue under collaboration agreement | \$ 3,474 | \$ 3,227 |
| Operating expenses: | | |
| Research and development | 10,021 | 7,893 |
| General and administrative | 3,173 | 2,510 |
| Total operating expenses | <u>13,194</u> | <u>10,403</u> |
| Loss from operations | (9,720) | (7,176) |
| Other income | 4 | 231 |
| Net loss and comprehensive loss | <u>\$ (9,716)</u> | <u>\$ (6,945)</u> |
| Net loss per share attributable to common stockholders basic and diluted | <u>\$ (2.52)</u> | <u>\$ (2.62)</u> |
| Weighted-average common stocks outstanding, basic and diluted | <u>3,850,264</u> | <u>2,655,767</u> |