



## Ikena Oncology Reports Third Quarter 2021 Financial Results and Corporate Update

November 10, 2021

*IND for IK-930 accepted by FDA; Phase 1 clinical trial expected to initiate in early 2022*

*Progressing RAS pathway research programs with multiple development candidates expected in the next 18 months*

*Investigator-initiated trial launched evaluating IK-007 in combination with eribulin in recurrent/metastatic inflammatory breast cancer*

BOSTON, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Ikena Oncology, Inc. (Nasdaq: IKNA, "Ikena", "Company"), a targeted oncology company focused on developing novel cancer therapies targeting key signaling pathways, today announced financial results for the quarter ended September 30, 2021. The Company also provided an update across the organization and pipeline, including the acceptance of an IND for their TEAD inhibitor, IK-930, as they advance it towards initiation of a Phase 1 clinical trial for patients with tumors known to have high incidence of Hippo pathway genetic alterations.

In addition to the Company's progress on IK-930, Ikena is driving several programs targeting the RAS pathway. Emerging data from discovery and translational efforts have focused the team on key nodes in the RAS pathway that provide potential for clinical advancement of targeted therapies both as single agents and in combination to overcome therapeutic resistance in RAS mutated cancers. This work includes further efforts on ERK5 biology and chemistry optimization prior to candidate nomination, but also highlights new opportunities in the pathway. Multiple development candidates are expected to emerge from these RAS discovery programs over the next 18 months.

"Patients with mutations in the Hippo and RAS pathways represent cancer populations with significant unmet needs. At Ikena, we are committed to generating deep scientific support for our approach in these pathways and in the identification of therapies that could best treat their individual disease," commented Mark Manfredi, Ph.D., Chief Executive Officer of Ikena. "The team has done tremendous work exploring TEAD biology, advancing IK-930, and generating robust translational data to optimize the clinical development plan. The IND acceptance is a foundational milestone for our targeted oncology portfolio and for our approach to biomarker-driven cancer treatments. The progress across the entirety of our pipeline demonstrates our commitment to science and medicine that will lead to better therapies with the best chance of helping patients."

### Summary of Recent Pipeline Progress and Corporate Update

#### • **IK-930: TEAD Inhibitor in the Hippo Signaling Pathway**

- [IND accepted by the Food and Drug Administration \(FDA\)](#); clinical trial expected to initiate in the first quarter of 2022
- Program [data was shared at the AACR-NCI-EORTC 2021](#) Virtual International Conference on Molecular Targets and Cancer Therapeutics
  - Data highlighted translational methods using a novel assay developed by Ikena and suggested YAP/TAZ activity could be a potential biomarker in determining patients that could benefit from TEAD inhibition
  - Preclinical data showed the importance of the Hippo pathway in resistance to EGFR and MEK inhibition and the potential of therapeutic combinations for patients, supporting our plans to evaluate combinations of IK-930 in multiple tumor types

#### • **RAS Pathway: Progressing Multiple Targets and Novel Approaches**

- Ikena has been expanding its discovery and translational research efforts in the RAS pathway beyond ERK5, with a particular focus on targeting nodes in the pathway that have potential for monotherapy and combinations both intra-pipeline and with other targeted agents
- Continued drug discovery and additional translational efforts are being conducted prior to potential ERK5 candidate nomination. The RAS pathway discovery programs are expected to result in multiple targeted oncology development candidates in the next 18 months

#### • **IK-175 & IK-412: AHR Inhibitor and Kynurenine Degrading Enzyme Programs in Collaboration with Bristol Myers Squibb**

- IK-175 is currently being evaluated in a Phase 1 study to assess its impact in solid tumors and in urothelial carcinoma through aryl hydrocarbon receptor (AHR) inhibition
  - The study expanded its monotherapy cohort in urothelial carcinoma earlier this year and recently completed

the dose escalation of the combination of IK-175 with nivolumab

- The combination arm expansion cohort in urothelial carcinoma is now open for enrollment, including nuclear AHR positive enriched subset of patients
- Three posters on [IK-175 will be presented at the Society for Immunotherapy of Cancer Conference](#) on November 12, 2021 highlighting translational data and a trial-in-progress presentation on the Phase 1 clinical trial design
- IK-175 clinical data presentation is planned for a major medical conference in 2022
- As previously reported, manufacturing lead times have been delayed for IK-412 and as such, Ikena and Bristol Myers Squibb are continuing to evaluate the best path forward
- **IK-007: EP4 Receptor Antagonist Currently in Phase 1 Clinical Trial**
  - The IK-007 Phase 1 study in MSS colorectal cancer is on track to complete enrollment by the end of 2021; data will be submitted to a medical conference in 2022
  - An investigator-initiated trial (IIT) of IK-007 in combination with the chemotherapy agent eribulin in metastatic inflammatory breast cancer (IBC) led by Naoto Ueno, M.D., of the University of Texas MD Anderson Cancer Center was launched in September 2021
    - IBC is a rare, aggressive form of breast cancer with high unmet medical need
    - Increased COX-2 expression in the EP4 pathway has been associated with poor prognosis in IBC patients
- **Organizational Growth: Addition of Senior Clinical and Research Expertise**

○ Ikena recently added deep expertise in clinical development, clinical operations, and cancer biology to the leadership team:

- Karim Malek, M.D.: Vice President, Clinical Development
  - Medical oncologist with over 30 years of experience both in the clinic and in research and development, with strong academic roots
  - Joined Ikena from Takeda Pharmaceuticals where he was the global clinical lead on multiple immune-oncology platforms and garnered an extensive background in clinical trial design and execution
- Jennifer Schroeder, PMP: SVP Clinical Development Operations
  - Seasoned executive with nearly 25 years of experience ranging from start-ups to Fortune 500 companies
  - Served over a decade with Pfizer and was one of the founding business process owners where she helped implement clinical trial management systems and directed a globally focused team of seven leading enterprise-scale projects
- Holly Koblisch, Ph.D.: Vice President, Cancer Biology
  - Over 20 years of experience in oncology drug discovery, asset development and target selection
  - Extensive drug discovery background as a pharmacology leader at Incyte, where she participated in the discovery of pemigatinib and capmatinib, two medicines recently approved in the U.S. and abroad

#### **Financial Results for the Quarter Ended September 30, 2021**

As of September 30, 2021, the Company had cash and cash equivalents totaling \$245.9 million, which will fund operations through 2023. Net cash used in operations was \$18.0 million for the third quarter of 2021 as compared to \$7.7 million for the third quarter of 2020.

Research and development expenses for the third quarter 2021 were \$13.4 million, compared to \$7.2 million for the third quarter 2020. The increase in research and development expense was primarily attributable to IND-enabling studies, manufacturing development costs and clinical trial start-up costs for IK-930, manufacturing costs for IK-175, the on-going IND-enabling studies for IK-412, and research activities for other discovery stage programs. In addition, research and development expenses related to personnel and overhead expenses increased due to an increase in headcount. This increase in research and development expenses was partially offset by a decrease in development activities for IK-007.

General and administrative expenses for the third quarter were \$4.9 million, compared to \$1.8 million for the third quarter 2020. The increase was primarily attributable to an increase in compensation expense due to an increase in headcount and in insurance expense, as well as general increases

in audit, legal, consulting and facilities expenses to support our operations as a public company.

Net loss for the third quarter 2021 was \$14.5 million, compared to \$6.2 million for the third quarter.

## About Ikena Oncology

Ikena Oncology is focused on developing novel therapies targeting key signaling pathways that drive the formation and spread of cancer. Ikena is advancing multiple programs that target tumor markers as well as programs targeting the tumor microenvironment. The Company's lead program, IK-930, is a TEAD inhibitor targeting the Hippo signaling pathway, a pathway that can drive formation and increase survival of tumors and also drives development of resistance to multiple existing therapies. Additional programs include those targeting the RAS signaling pathway and several programs targeting the tumor microenvironment and immune signals, two of which are being developed in collaboration with Bristol Myers Squibb. Ikena's pipeline is built on targeting 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](http://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 the timing of the expansion of the monotherapy cohort for IK-175; the future availability of key components in the manufacture of IK-412; our expectations regarding delays in our clinical trials, including for IK-412; our expectations regarding the progression of our preclinical studies, including IND-enabling studies for IK-412; our expectations regarding the timing of presentation of preclinical and clinical data, including the timing of the clinical trial for IK-930; 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 ability to demonstrate 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; 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 and should not be relied on as representing our views as of any subsequent date. 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.

### Condensed Consolidated Balance Sheet Data (Unaudited) (in thousands)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 245,899	\$ 162,491
Total assets	261,705	168,404
Total liabilities	58,442	63,473
Redeemable convertible preferred stock	-	205,979
Additional paid-in-capital	351,478	10,288
Accumulated deficit	(148,251)	(111,339)
Total stockholders' equity (deficit)	203,263	(101,048)

### Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) (in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development revenue under collaboration agreement	\$ 3,746	\$ 2,829	\$ 10,768	\$ 9,129
Operating expenses:				
Research and development	13,375	7,218	34,770	21,445
General and administrative	4,893	1,844	12,928	6,150
Total operating expenses	18,268	9,062	47,698	27,595

Loss from operations	(14,522)	(6,233)	(36,930)	(18,466)
Other income	7	11	18	261
Net loss and comprehensive loss	<u>\$ (14,515)</u>	<u>\$ (6,222)</u>	<u>\$ (36,912)</u>	<u>\$ (18,205)</u>
Net loss per share attributable to common stockholders basic and diluted	<u>\$ (0.40)</u>	<u>\$ (2.34)</u>	<u>\$ (1.46)</u>	<u>\$ (6.85)</u>
Weighted-average common stocks outstanding, basic and diluted	<u>35,860,284</u>	<u>2,658,800</u>	<u>25,305,212</u>	<u>2,657,793</u>

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