Ikena Oncology Reports Second Quarter 2021 Financial Results and Provides Update on Key Programs

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IK-930 IND on track for submission in 2021; multiple upcoming preclinical and translational conference presentations on TEAD inhibition by IK-930

Progressing IK-175 clinical trial monotherapy expansion cohort in bladder cancer patients

Continued progress across targeted oncology pipeline towards research and clinical milestones

BOSTON, Aug. 12, 2021 (GLOBE NEWSWIRE) -- Ikena Oncology, Inc. (Nasdaq: IKNA, "Ikena"), a targeted oncology company focused on developing novel cancer therapies targeting key signaling pathways, today announced financial results for the quarter that ended June 30, 2021. The Company also shared updates on several pipeline programs targeting tumor signaling pathways, including Hippo, RAS, and the tumor microenvironment.

"In recent months, the Ikena team has continued to generate data on the important targets we are exploring and our development candidates. This work has further elucidated the potential of TEAD inhibition as a monotherapy and in combination with other targeted therapies, and enables us to further refine the clinical development strategy for IK-930, our novel TEAD inhibitor," said Mark Manfredi, PhD, Chief Executive Officer of Ikena Oncology. "We look forward to sharing these and more updates as our data matures and we make strides towards our goal to transform the landscape of cancer treatment to a targeted, patient-focused treatment paradigm."

Ikena is also evaluating our novel AHR antagonist, IK-175, in a Phase I clinical trial as a monotherapy and in combination with nivolumab for the treatment of advanced or metastatic solid tumors, including in urothelial carcinoma, a type of bladder cancer where there is a significant unmet need. After completing the monotherapy dose escalation we are progressing the expansion cohort and enrolling additional urothelial carcinoma patients to continue evaluating IK-175 as a monotherapy and the path towards proof-of-concept in this patient population.

"The emerging clinical data observed for IK-175 monotherapy in urothelial carcinoma and the expansion of the cohort are great steps toward establishing proof of concept. These patients have very limited options for treatment, and we are hopeful that IK-175 could have significant impact in this setting," said Sergio Santillana, MD, Chief Medical Officer at Ikena. "The monotherapy cohort expansion is an encouraging development for the Ikena team and ultimately for the patients whose cancer could be treated with this novel therapy. We look forward to generating additional data and providing an update on safety and preliminary anti-tumor activity of IK-175 at a medical conference in 2022."

Recent Pipeline Progress and Corporate Update

- **IK-930: TEAD Inhibitor in the Hippo Signaling Pathway in IND-enabling Studies**
  - IND-enabling studies continued to progress and the IND submission is on track for the end of 2021.
  - Translational and preclinical data will be shared at the EORTC-NCI-AACR 2021 Virtual International Conference on Molecular Targets and Cancer Therapeutics taking place October 7-10, 2021.
    - Virtual Poster Presentation of IK-930 indication selection methodology and data, highlighting a novel method to assess activation across the Hippo pathway and the rationale behind mesothelioma as a cancer type that could benefit from TEAD inhibition as a monotherapy
    - Virtual Poster Presentation of the tumor growth inhibition observed in *in vivo* preclinical models of lung and colon cancer with IK-930 combined with inhibition of MEK and EGFR, separately and in triplet
- **IK-175: Clinical Stage AHR Antagonist Partnered with Bristol Myers Squibb (BMS)**
  - Ikena is expanding the monotherapy bladder cancer cohort to treat additional patients in the current dose expansion cohort per protocol of the ongoing Phase 1 clinical trial.
  - Translational and preclinical data will be shared at scientific conferences in the second half of 2021.
  - Clinical data presentation planned for a major medical conference in 2022.
- **IK-412: Novel Enzymatic Therapeutic Degrading Kynurenine Partnered with BMS**
  - Ikena was notified in the second quarter that a key component required in the manufacturing of IK-412 is also required for the manufacturing of COVID-19 vaccines and therapies. As a result, the availability of the component for purposes other than vaccine production is extremely limited in the near-term.
    - This situation impacted our manufacturing lead times, delaying the planned IND submission for IK-412.
    - Updated guidance on IND submission timing will be provided when material supply of this key component can be reliably projected.

- We continue to work closely with our supplier and contract manufacturing organization, as well as our partner BMS, to advance the program toward IND submission.

- IND-enabling studies of IK-412 continue to progress as planned.

- **Additional Pipeline Programs Continue to Progress**

Financial Results for the Quarter Ended June 30, 2021

As of June 30, 2021, the Company had cash and cash equivalents totaling $264.0 million, which will fund operations through 2023. Net cash used in operations was $15.7 million for the second quarter of 2021 as compared to $7.7 million for the second quarter of 2020.

Research and development expenses for the second quarter 2021 were $11.4 million, compared to $6.3 million for the second quarter 2020. The increase in R&D expense was primarily related to on-going IND-enabling studies and manufacturing development costs for IK-930, ongoing IND-enabling studies for IK-412, increased research activities of other discovery stage programs and increased personnel expenses due to increase in headcount. The increase in research and development expenses was offset by a decrease in expense attributable to drug manufacturing of IK-175 and a decrease in clinical activities for IK-007.

General and administrative expenses for the second quarter were $4.9 million, compared to $1.8 million for the second quarter 2020. The increase in G&A expense was 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 operations as a public company.

Net loss for the second quarter 2021 was $12.7 million, compared to $5.0 million for the second quarter 2020, driven by increases in research and development and general and administrative expenses.

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 an ERK5 inhibitor program targeting the KRAS 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 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; 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)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 264,004	$ 162,491
Total assets	278,827	168,404
Total liabilities	62,567	63,473
Redeemable convertible preferred stock	-	205,979
Additional paid-in-capital	349,960	10,288
Accumulated deficit	(133,736)	(111,339)

Total stockholders' equity (deficit)	216,260	(101,048)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development revenue under collaboration agreement	$ 3,549	$ 3,073	$ 7,023	$ 6,300
Operating expenses:				
Research and development	11,374	6,334	21,396	14,226
General and administrative	4,862	1,798	8,035	4,308
Total operating expenses	16,236	8,132	29,431	18,534
Loss from operations	(12,687)	(5,059)	(22,408)	(12,234)
Other income (expense), net	6	21	11	251
Net loss and comprehensive loss	$ (12,681)	$ (5,038)	$ (22,397)	$ (11,983)
Net loss per share attributable to common stockholders basic and diluted	$ (0.35)	$ (1.89)	$ (1.12)	$ (4.51)
Weighted-average common stocks outstanding, basic and diluted	35,853,341	2,658,800	19,940,204	2,657,283

Media Contact:
Gwen Schanker
LifeSci Communications
gschanker@lifescicomms.com

Investor Contact:
Rebecca Cohen
Ikena Oncology
rcohen@ikenaoncology.com