Ikena Oncology Reports Fourth Quarter and Full Year 2022 Financial Results

March 14, 2023

Focused targeted oncology pipeline advancing towards multiple near-term milestones; runway into 2025

Novel paralog-selective TEAD inhibitor, IK-930, advanced through multiple dose escalation cohorts, Fast Track and Orphan designations granted; initial clinical data planned for 2H 2023

Nominated potential best-in-class MEK-RAF complex inhibitor, IK-595; advancing towards IND in 2H 2023

Presented positive data from IK-175 Phase 1b clinical trial in urothelial carcinoma; Fast Track designation recently granted for combination with immune checkpoint inhibitors

BOSTON, March 14, 2023 (GLOBE NEWSWIRE) -- Ikena Oncology, Inc. (Nasdaq: IKNA, “Ikena”, “Company”), a targeted oncology company navigating new territory in patient-directed cancer treatment, today announced financial results for the fourth quarter and full year ending December 31, 2022. The Company also provided an update across the organization and pipeline.

“We’re thrilled to report the meaningful progress made in 2022 across our entire pipeline. We continued our leadership in the Hippo space last year, advancing IK-930 and furthering our deep knowledge in the pathway biology and its relationships within the onco-signaling network. We are looking forward to sharing more on IK-930’s differentiation in the coming months and our initial clinical data from the program later this year,” said Mark Manfredi, Ph.D., Chief Executive Officer of Ikena. “In 2022 we also advanced our efforts in the RAS pathway – one of the highest spaces of unmet medical need – with our nomination of IK-595, targeting MEK-RAF. We designed IK-595 to specifically address the biggest shortcomings of existing inhibitors. Our team has generated a rich body of data supporting IK-595 as a differentiated therapy for multiple patient populations with RAS mutated cancers. We are looking forward to a robust 2023, with expected milestones across our pipeline, reinforcing our commitment to advancing innovative therapies for patients in need.”

Recent Pipeline Progress & Corporate Update

- **IK-930: Paralog-Selective TEAD Inhibitor in the Hippo Signaling Pathway**
  - Phase 1 trial of IK-930 in Hippo altered cancers (NCT05228015) continues to advance as expected, with multiple dose escalation cohorts cleared
  - In March 2022, the FDA granted IK-930 orphan designation as a potential novel treatment in mesothelioma, and granted IK-930 Fast Track designation in NF2 mesothelioma in June 2022
  - Preclinical data presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2022 and at the EORTC-NCI-AACR Triple Meeting in October 2022 demonstrated the potential of the IK-930 combination strategy with other targeted therapies to combat therapeutic resistance, including data demonstrating combination therapy with IK-930 and EGFR inhibitors reduced the prevalence of refractory *persister* cells, a subpopulation of cells that can drive resistance to therapies
  - Plan to present advantages of IK-930 paralog selectivity, including nonclinical toxicity studies in multiple models showing significantly superior tolerability over pan-TEAD inhibitors, at upcoming 2023 AACR Annual Meeting in April
  - Initial clinical data from the monotherapy portion of the Phase 1 study is expected in the second half of 2023
- **IK-595: MEK-RAF Inhibitor in the RAS Signaling Pathway**
  - IK-595, nominated as a development candidate in November 2022, is designed to achieve novel inhibition of MEK-RAF by trapping them in an inactive complex, more effectively achieving pathway inhibition than existing inhibitors, particularly by complexing CRAF
  - Presented preclinical data demonstrating differentiation of IK-595 at recent AACR Special Meeting: Targeting RAS; data included studies demonstrating:
    - Potent, durable inhibition capabilities of IK-595 through multiple biochemical and cellular assays, including measuring phosphorylation and activation of MEK and ERK, as well as downstream target gene expression
    - Differentiation through CRAF stabilizing with MEK, potentially preventing both CRAF kinase-independent

anti-apoptotic function in RAS/RAF mutated cancers and CRAF signaling bypass mechanism, which cancer cells employ to drive therapeutic resistance to other drugs in this class

- IK-595 preclinical efficacy in RAS and RAF altered cancer cell lines as a monotherapy and *in vitro* synergy with potential combination agents
- Projected pharmacokinetics and pharmacodynamics of IK-595 to optimize therapeutic window, a key factor in the area of MEK inhibition

- Investigational new drug application (IND) submission for IK-595 to the U.S. Food & Drug Administration (FDA) planned for the second half of 2023

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

  - Ongoing Phase 1a/1b clinical trial evaluating IK-175 as a monotherapy and in combination with nivolumab in patients with advanced or metastatic solid tumors, including urothelial carcinomas

    - In February 2023, the FDA granted Fast Track designation to IK-175 in combination with immune checkpoint inhibitors for patients with advanced urothelial cancer who have progressed on or within 3 months of receiving the last dose of an immune checkpoint inhibitor
    - Initial clinical data from the program was presented in November 2022 at the Society for Immunotherapy of Cancer Annual Meeting and showed encouraging antitumor activity of IK-175 in urothelial carcinoma
      - Data included a 40% disease control rate and 20% overall response rate in urothelial carcinoma patients who received IK-175 in combination with immune checkpoint inhibitors, with the majority of combination patients experiencing reduction in their target lesions
    - The program is eligible for opt-in from Bristol Myers Squibb through early 2024

- **Corporate Highlights**

  - Cash, cash equivalents, and marketable securities as of December 31, 2022 were $156.9 million, providing projected runway into 2025
  - Appointed Owen Hughes as Chair of the Board of Directors in December 2022, bringing operations and public company experience to the role

Financial Results for the Year Ended December 31, 2022

As of December 31, 2022, Ikena had $156.9 million in cash, cash equivalents, and marketable securities, and believes this will be sufficient to meet its operating requirements into 2025. Net cash used in operating activities was $74.1 million for the year ended December 31, 2022, as compared to $60.3 million of cash used in operating activities for the same period in 2021.

Research and development revenue under collaboration agreement of $15.6 million and $31.0 million for the year ended December 31, 2022 and 2021, respectively, is related to the BMS Collaboration Agreement for the IK-175 and IK-412 programs which was executed in January 2019. The decrease in revenue during the year ended December 31, 2022, as compared to the same period in the prior year, was primarily due to change in estimate of the total services to be performed on the IK-412 program during the remainder of the BMS Collaboration Agreement term.

Research and development expenses were $64.3 million and $47.1 million for the year ended December 31, 2022 and 2021, respectively. The increase in research and development expense of $17.2 million was primarily attributable to employee-related expenses due to an increase in headcount, research activities, and consulting services for the Company's development candidate IK-595, and increased clinical trial costs for IK-930.

General and administrative expenses were $22.2 million and $18.0 million for the year ended December 31, 2022 and 2021, respectively. The increase in general and administrative expense of $4.2 million was primarily attributable to an increase in compensation and benefit related expenses due to an increase in headcount.

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 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 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 progress and timing of updates on the clinical development of the

programs in our portfolio, including the timing of clinical data updates for IK-930, IK-595, IK-175 and preclinical discovery programs in targeted oncology; 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; expectations regarding our cash runway projection; 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, and other factors discussed in the "Risk Factors" section of Ikena's Quarterly Report on 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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Financial Tables

Selected Financial Information
(in thousands, except share and per share data)

Statement of Operations Items:	**Three Months Ended December 31,**		**Year Ended December 31,**	
	2022	**2021**	**2022**	**2021**
Research and development revenue under collaboration agreement	$ 5,450	$ 20,217	$ 15,618	$ 30,985
Operating expenses:				
Research and development	15,640	12,338	64,321	47,108
General and administrative	4,925	5,088	22,201	18,015
Total operating expenses	20,565	17,426	86,522	65,123
Income (loss) from operations	(15,115)	2,791	(70,904)	(34,138)
Other income (expense)				
Interest income	893	5	2,149	23
Other income (expense)	123	—	(10)	—
Total other income, net	1,016	5	2,139	23
Net income (loss)	$ (14,099)	$ 2,796	$ (68,765)	$ (34,115)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	418	—	(763)	—
Total comprehensive income (loss)	$ (13,681)	$ 2,796	$ (69,528)	$ (34,115)
Net income (loss) per share:				
Basic	$ (0.39)	$ 0.08	$ (1.90)	$ (1.22)
Diluted	$ (0.39)	$ 0.07	$ (1.90)	$ (1.22)
Weighted-average common stocks outstanding				
Basic	36,257,493	35,930,467	36,188,420	27,983,359
Diluted	36,257,493	37,897,437	36,188,420	27,983,359

Selected Balance Sheet Items:	**December 31, 2022**	**December 31, 2021**
Cash and cash equivalents	$ 59,919	$ 232,217
Marketable securities	$ 97,028	$ -

Total assets	$	172,259	$	247,879
Total liabilities	$	25,290	$	40,002
Additional paid-in-capital	$	361,915	$	353,295
Accumulated deficit	$	(214,219)	$	(145,454)
Total stockholders' equity	$	146,969	$	207,877