ORIC Pharmaceuticals Reports Third Quarter 2023 Financial Results and Operational Updates

November 6, 2023 at 4:10 PM EST

Presented initial Phase 1b data for ORIC-114 in patients with EGFR and HER2 Exon 20 mutated NSCLC demonstrating potential best-in-class profile

Initial Phase 1b data for ORIC-533 in patients with multiple myeloma to be presented at the 65th ASH Annual Meeting being held December 9-12, 2023

Initial Phase 1b data for ORIC-944 in patients with prostate cancer expected in first quarter of 2024

Cash and investments of $256.2 million expected to fund operating plan into late 2025

SOUTH SAN FRANCISCO and SAN DIEGO, Nov. 06, 2023 (GLOBE NEWSWIRE) -- ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today reported financial results and operational updates for the quarter ended September 30, 2023.

"We continued making strong progress across our pipeline in the third quarter of 2023 with steady enrollment across our three clinical trials and the first presentation of clinical data for ORIC-114," said Jacob M. Chacko, MD, chief executive officer. "Initial data for ORIC-114 demonstrated clinical activity across multiple dose levels, including the first reported CNS complete response by an EGFR exon 20 inhibitor in a patient with untreated brain metastases, and a favorable safety profile. We are eager to continue advancing ORIC-114, and we also look forward to presenting initial clinical data for ORIC-533 in multiple myeloma and for ORIC-944 in prostate cancer over the coming quarters."

Third Quarter 2023 and Other Recent Highlights:

ORIC-114: a brain penetrant, orally bioavailable, irreversible EGFR/HER2 inhibitor

- Presented initial data from the ongoing Phase 1b dose escalation trial for patients with EGFR or HER2 exon 20 mutated non-small cell lung cancer (NSCLC) at the ESMO Congress 2023.
  - CNS activity was observed at multiple dose levels, including the first reported CNS complete response by an EGFR exon 20 inhibitor in a patient with documented untreated brain metastases.
  - Systemic responses were observed at multiple dose levels in heavily pre-treated NSCLC patients, characterized by 81% having received prior EGFR exon 20 targeted agents and 86% having CNS metastases at baseline.
  - At the potential RP2D of 75 mg QD, responses were observed in 2 of 3 EGFR exon 20 patients previously treated with amivantamab, including a confirmed complete response.
  - Responses were observed at multiple dose levels in HER2 exon 20 patients, including a confirmed partial response with 100% regression of all target lesions.
  - ORIC-114 demonstrated a favorable safety profile with mainly Grade 1 and 2 treatment related adverse events.
- Presented preclinical data for ORIC-114 at ESMO Congress 2023 demonstrating potent activity across atypical mutations in EGFR.
- The Phase 1b trial of ORIC-114 is ongoing to determine the candidate RP2Ds for dose optimization and the selection of the final RP2D. Expansion cohorts will enroll patients with EGFR exon 20 insertion mutations that are EGFR exon 20 inhibitor-naïve and that have been previously treated with amivantamab, as well as patients with HER2 exon 20 insertion mutations and atypical EGFR mutations. The company expects to report updated Phase 1b data in the first half of 2025.

ORIC-533: a highly potent, orally bioavailable small molecule inhibitor of CD73

- Ongoing enrollment in a Phase 1b trial of ORIC-533 in patients with relapsed/refractory multiple myeloma.
- The company will report initial safety, PK/PD, and preliminary antitumor activity data at the 65th ASH Annual Meeting taking place December 9-12, 2023, in San Diego, CA.

ORIC-944: a potent and selective allosteric inhibitor of PRC2

- Ongoing enrollment in a Phase 1b trial of ORIC-944 in patients with advanced prostate cancer.
- Expect to report initial safety, PK/PD, and preliminary antitumor activity data in the first quarter of 2024.

Third Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Investments**: Cash, cash equivalents and investments totaled $256.2 million as of September 30, 2023, which the company expects will be sufficient to fund its current operating plan into late 2025.
- **R&D Expenses**: Research and development (R&D) expenses were $22.4 million for the three months ended September 30, 2023, compared to $14.7 million for the three months ended September 30, 2022, an increase of $7.7 million. For the

nine months ended September 30, 2023, R&D expenses were $60.7 million, compared to $45.4 million for the nine months ended September 30, 2022, an increase of $15.3 million. The increases were due to a net increase in external expenses related to the advancement of product candidates and discovery programs, as well as higher personnel costs.

- **G&A Expenses**: General and administrative (G&A) expenses were $6.3 million for the three months ended September 30, 2023, compared to $6.0 million for the three months ended September 30, 2022, an increase of $0.3 million. For the nine months ended September 30, 2023, G&A expenses were $18.7 million, compared to $19.3 million for the nine months ended September 30, 2022, a decrease of $0.6 million. The decrease was primarily due to a decrease in professional fees.
- **IPR&D Expenses**: Acquired in-process research and development (IPR&D) expenses of $5.0 million for the three and nine months ended September 30, 2022, were due to a development milestone payment related to ORIC-114. There were no such expenses for the three and nine months ended September 30, 2023.

About ORIC Pharmaceuticals, Inc.

ORIC Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to improving patients' lives by *Overcoming Resistance In Cancer*. ORIC's clinical stage product candidates include (1) ORIC-114, a brain penetrant inhibitor designed to selectively target EGFR and HER2 with high potency against exon 20 insertion mutations, being developed across multiple genetically defined cancers, (2) ORIC-533, an orally bioavailable small molecule inhibitor of CD73, a key node in the adenosine pathway believed to play a central role in resistance to chemotherapy- and immunotherapy-based treatment regimens, being developed for multiple myeloma, and (3) ORIC-944, an allosteric inhibitor of the polycomb repressive complex 2 (PRC2) via the EED subunit, being developed for prostate cancer. Beyond these three product candidates, ORIC is also developing multiple precision medicines targeting other hallmark cancer resistance mechanisms. ORIC has offices in South San Francisco and San Diego, California. For more information, please go to www.oricpharma.com, and follow us on X or LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the continued clinical development of ORIC-114; ORIC-114 clinical outcomes, which may materially change as patient enrollment continues or more patient data become available; the development plans for ORIC-114 and ORIC's other product candidates; the potential advantages of ORIC-114 and ORIC's other product candidates and programs; plans underlying ORIC's clinical trials and development; the expected timing of reporting initial data from the ORIC-533 and ORIC-944 clinical trials; the expected timing of reporting updated Phase 1b data from the ORIC-114 clinical trial; the period over which ORIC estimates its existing cash, cash equivalents and investments will be sufficient to fund its current operating plan; and statements by the company's chief executive officer. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. The forward-looking statements contained herein are based upon ORIC's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those projected in any forward-looking statements due to numerous risks and uncertainties, including but not limited to: risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and operating as an early clinical stage company; ORIC's ability to develop, initiate or complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of its product candidates; changes in ORIC's plans to develop and commercialize its product candidates; the potential for clinical trials of ORIC-114, ORIC-533, ORIC-944 or any other product candidates to differ from preclinical, initial, interim, preliminary or expected results; negative impacts of health emergencies, economic instability or international conflicts on ORIC's operations, including clinical trials; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of ORIC's license and collaboration agreements; the potential market for our product candidates, and the progress and success of competing therapeutics currently available or in development; ORIC's ability to raise any additional funding it will need to continue to pursue its business and product development plans; regulatory developments in the United States and foreign countries; ORIC's reliance on third parties, including contract manufacturers and contract research organizations; ORIC's ability to obtain and maintain intellectual property protection for its product candidates; the loss of key scientific or management personnel; competition in the industry in which ORIC operates; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in ORIC's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 6, 2023, and ORIC's future reports to be filed with the SEC. These forward-looking statements are made as of the date of this press release, and ORIC assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

Contact:
Dominic Piscitelli, Chief Financial Officer
dominic.piscitelli@oricpharma.com
info@oricpharma.com

ORIC PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 227,296	$ 206,272
Prepaid expenses and other current assets	4,940	4,185

Total current assets	232,236	210,457
Long-term investments	28,867	21,951
Property and equipment, net	3,062	3,253
Other assets	10,170	11,517
Total assets	$ 274,335	$ 247,178
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,736	$ 1,320
Accrued liabilities	15,208	14,068
Total current liabilities	18,944	15,388
Other long-term liabilities	7,977	9,439
Total liabilities	26,921	24,827
Total stockholders' equity	247,414	222,351
Total liabilities and stockholders' equity	$ 274,335	$ 247,178

ORIC PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 22,388	$ 14,723	$ 60,691	$ 45,385
General and administrative	6,294	5,971	18,661	19,263
Acquired in-process research and development	—	5,000	—	5,000
Total operating expenses	28,682	25,694	79,352	69,648
Loss from operations	(28,682)	(25,694)	(79,352)	(69,648)
Other income, net	3,204	865	6,985	1,373
Net loss	$ (25,478)	$ (24,829)	$ (72,367)	$ (68,275)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	198	(516)	922	(1,644)
Comprehensive loss	$ (25,280)	$ (25,345)	$ (71,445)	$ (69,919)
Net loss per share, basic and diluted	$ (0.44)	$ (0.63)	$ (1.46)	$ (1.73)
Weighted-average shares outstanding, basic and diluted	57,402,226	39,575,660	49,424,418	39,496,864