



ORIC Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Operational Update

March 21, 2022 at 4:00 PM EDT

Announces decision to discontinue development of ORIC-101

Company will focus on advancing its three single agent Phase 1 programs, ORIC-533 in multiple myeloma, ORIC-114 in EGFR/HER2 cancers, and ORIC-944 in prostate cancer, with initial data expected from the three programs in 1H 2023

With cash and investments of \$280.4 million, cash runway extended into 2H 2024

Conference call and webcast today at 5:00 p.m. ET

SOUTH SAN FRANCISCO Calif. and SAN DIEGO, March 21, 2022 (GLOBE NEWSWIRE) -- ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today announced the discontinuation of ORIC-101 and also reported financial results and operational updates for the quarter and year ended December 31, 2021. The company conducted planned interim analyses of two Phase 1b studies and concluded that ORIC-101 did not demonstrate sufficient clinical activity to warrant further development.

"We are disappointed in the outcome of the ORIC-101 studies in combination with nab-paclitaxel in various solid tumors and in combination with enzalutamide in metastatic prostate cancer, two late-line patient populations for whom limited treatment options exist today. We believe both studies were well designed, allowing us to thoroughly and efficiently answer an important clinical question. With this decision to discontinue ORIC-101 development, we would like to thank the investigators, site staff, the ORIC team, and most importantly, patients and families who participated in the trials," said Pratik S. Multani, MD, chief medical officer.

"We've always been committed to rapid, data driven decision making and allocating resources efficiently and prudently," said Jacob M. Chacko, MD, chief executive officer, "We intentionally built a diverse pipeline of differentiated programs, which includes our Phase 1b single agent trials for ORIC-533, our orally bioavailable CD73 inhibitor, ORIC-114, our brain penetrant EGFR/HER2 inhibitor, and ORIC-944, our embryonic ectoderm development (EED) inhibitor. We expect to report initial data from each study in the first half of 2023. As a result of the ORIC-101 discontinuation, we project our cash runway to extend into the second half of 2024, well beyond the planned initial data disclosures from these three clinical programs."

Fourth Quarter 2021 and Other Recent Highlights

ORIC-101: Glucocorticoid Receptor Antagonist

Based on interim analyses from the two Phase 1b studies, ORIC-101 did not demonstrate sufficient clinical activity and, therefore, the company has discontinued further development.

The dose expansion portion of the Phase 1b clinical trial of ORIC-101 in combination with enzalutamide enrolled 28 patients at the recommended phase 2 dose (RP2D) with metastatic prostate cancer progressing on enzalutamide. The RP2D was well tolerated with a safety profile consistent with previously reported results. ORIC-101 in combination with enzalutamide did not translate into a meaningful clinical benefit, with a median progression-free survival (PFS) in the target patient population of 3.7 months.

The dose expansion portion of the Phase 1b clinical trial of ORIC-101 in combination with nab-paclitaxel enrolled 61 patients at the RP2D across four cohorts: pancreatic ductal adenocarcinoma (PDAC), ovarian cancer, triple negative breast cancer (TNBC), and other advanced solid tumors. The RP2D was well tolerated with a safety profile consistent with previously reported results. There were no objective responses in the PDAC cohort (n=21) and there was one confirmed partial response in the ovarian cancer cohort (n=13). There was no meaningful clinical benefit based on median PFS across all cohorts (PDAC: 1.9 months, and ovarian cancer: 2.2 months).

ORIC-533: CD73 Inhibitor

ORIC-533 is a highly potent, orally bioavailable small molecule inhibitor of CD73 and has demonstrated more potent adenosine inhibition in preclinical studies compared to an antibody approach and other small molecule inhibitors of the adenosine pathway.

- Ex vivo human data supporting the therapeutic potential of single agent ORIC-533 in multiple myeloma were presented at the American Society of Hematology annual meeting.
- Single agent activity in an autologous bone marrow mononuclear assay system from multiple myeloma patients showed CD73 inhibition compared favorably to approved therapies for the treatment of multiple myeloma, including lenalidomide, bortezomib and daratumumab.
- A Phase 1b trial with ORIC-533 as a single agent in multiple myeloma is enrolling patients and initial data are expected to be reported in the first half of 2023.

ORIC-114: EGFR/HER2 Inhibitor

ORIC-114 is a brain penetrant, orally bioavailable, irreversible inhibitor designed to selectively target EGFR and HER2 with high potency against exon 20 insertion mutations.

- Compelling brain exposure and antitumor activity of ORIC-114 in preclinical studies of HER2-positive breast cancer were presented at AACR-NCI-EORTC.
- Head-to-head data in an EGFR exon 20 NSCLC xenograft model were disclosed demonstrating good tolerability and improved efficacy, including a 90% complete response rate, with ORIC-114 versus multiple clinical stage exon 20 inhibitors.
- The Clinical Trial Application (CTA) for ORIC-114 was filed in the fourth quarter of 2021 and was cleared by the regulatory authorities of the Republic of Korea in the first quarter of 2022.
- A Phase 1b trial with ORIC-114 as a single agent has been initiated and will enroll patients with advanced solid tumors with EGFR or HER2 exon 20 alterations or HER2 amplification and will allow patients with CNS metastases that are either treated or untreated but asymptomatic. The company expects to report initial Phase 1b data from this trial in the first half of 2023.

ORIC-944: PRC2 Inhibitor

ORIC-944 is a potent and selective allosteric inhibitor of polycomb repressive complex 2 (PRC2) that targets its regulatory embryonic ectoderm development (EED) subunit and has demonstrated single agent efficacy in multiple enzalutamide-resistant prostate cancer models in preclinical studies.

- The IND for ORIC-944 was cleared by the FDA in the fourth quarter of 2021.
- A Phase 1b trial with ORIC-944 as a single agent will enroll patients with metastatic prostate cancer. The company expects to report initial Phase 1b data from this trial in the first half of 2023.

PLK4 Inhibitor Program

In March, the company announced a small molecule therapeutic program intended to address a mechanism of innate resistance found in a subset of breast cancers, specifically a synthetic lethal interaction of polo-like kinase 4 (PLK4) inhibition in tumors bearing a TRIM37 DNA amplification. Breast cancer models as well as other tumor models with this TRIM37 amplification have a key tumor dependency on PLK4 and our therapeutic approach is to selectively inhibit this enzyme.

Corporate

In November 2021, the company appointed Angie You, PhD, to its board of directors. Dr. You was most recently CEO of Amunix Pharmaceuticals, which was acquired by Sanofi, and brings broad experience spanning venture capital, business development and public company leadership roles.

Anticipated Program Milestones

ORIC anticipates the following upcoming milestones:

- ORIC-533: Initial Phase 1b data in 1H 2023
- ORIC-114: Initial Phase 1b data in 1H 2023
- ORIC-944: Initial Phase 1b data in 1H 2023

Fourth Quarter and Full year 2021 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments totaled \$280.4 million as of December 31, 2021, and with the discontinuation of ORIC-101, the company expects its cash runway to be extended into the second half of 2024.
- **R&D Expenses:** Research and development (R&D) expenses were \$16.7 million for the three months ended December 31, 2021, compared to \$12.1 million for the three months ended December 31, 2020, an increase of \$4.6 million. For the year ended December 31, 2021, R&D expenses were \$56.9 million compared to \$35.9 million for the same period of 2020, an increase of \$20.9 million. The increases for the 2021 periods were primarily driven by an increase in external expenses related to the advancement of ORIC-101, ORIC-533 and our other product candidates, as well as higher personnel costs, including additional non-cash stock-based compensation of \$0.7 million and \$2.9 million for the three and twelve months ended December 31, 2021, as compared to the same periods in 2020, respectively.
- **G&A Expenses:** General and administrative (G&A) expenses were \$6.1 million for the three months ended December 31, 2021, compared to \$4.3 million for the three months ended December 31, 2020, an increase of \$1.8 million. For the year ended December 31, 2021, G&A expenses were \$22.0 million compared to \$13.4 million for the same period in 2020, an increase of \$8.6 million. These increases were primarily due to higher personnel costs, including additional non-cash stock-based compensation of \$1.1 million and \$4.6 million for the three and twelve months ended December 31, 2021, as compared to the same periods in 2020, respectively, and higher costs related to operating as a public company.

Webcast and Conference Call

ORIC will host a conference call and webcast today at 5:00 p.m. ET. To participate in the conference call, please dial (833) 651-0991 (domestic) or (918) 922-6080 (international) and refer to conference ID 8637367. A live webcast and audio archive of the conference call will be available through the investor section of the company's website at www.oricpharma.com. The webcast will be available for replay for 90 days following the presentation.

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-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, (2) 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, 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 four 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 [Twitter](#) 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 ORIC's development plans and timelines; the potential advantages of ORIC's product candidates and programs; plans underlying ORIC's clinical trials and development; the expected timing of reporting initial data from the ORIC-533, ORIC-114 and ORIC-944 clinical trials; plans underlying any of ORIC's other programs; ORIC's anticipated milestones; 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 medical officer and 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-533, ORIC-114, ORIC-944 or any other product candidates to differ from preclinical, interim, preliminary or expected results; negative impacts of the COVID-19 pandemic 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 agreements; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 21, 2022, 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.

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

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 236,979	\$ 293,600
Prepaid expenses and other current assets	3,543	3,097
Total current assets	240,522	296,697
Investments, available-for-sale	43,386	—
Property and equipment, net	2,413	1,981
Other assets	12,321	319
Total assets	\$ 298,642	\$ 298,997
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,886	\$ 757
Accrued liabilities	13,265	8,245
Total current liabilities	15,151	9,002
Other long-term liabilities	10,515	219
Total liabilities	25,666	9,221

Total stockholders' equity	272,976	289,776
Total liabilities and stockholders' equity	<u>\$ 298,642</u>	<u>\$ 298,997</u>

ORIC PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 16,745	\$ 12,113	\$ 56,858	\$ 35,921
General and administrative	6,060	4,297	22,013	13,422
Acquired in-process research and development	—	11,872	—	24,843
Total operating expenses	<u>22,805</u>	<u>28,282</u>	<u>78,871</u>	<u>74,186</u>
Loss from operations	(22,805)	(28,282)	(78,871)	(74,186)
Other income:				
Interest income, net	34	30	141	306
Other	—	(7)	15	177
Total other income	<u>34</u>	<u>23</u>	<u>156</u>	<u>483</u>
Net loss	<u>\$ (22,771)</u>	<u>\$ (28,259)</u>	<u>\$ (78,715)</u>	<u>\$ (73,703)</u>
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(101)	(2)	(72)	(31)
Comprehensive loss	<u>\$ (22,872)</u>	<u>\$ (28,261)</u>	<u>\$ (78,787)</u>	<u>\$ (73,734)</u>
Net loss per share, basic and diluted	<u>\$ (0.58)</u>	<u>\$ (0.84)</u>	<u>\$ (2.07)</u>	<u>\$ (3.36)</u>
Weighted-average shares outstanding, basic and diluted	<u>39,386,166</u>	<u>33,618,477</u>	<u>37,954,280</u>	<u>21,942,476</u>