



ORIC Pharmaceuticals Reports Second Quarter 2021 Financial Results and Operational Update

August 10, 2021

ORIC-101 on track for initial Phase 1b data readout in prostate cancer in 2H21

ORIC-533 IND cleared by FDA; initiation of Phase 1 trial expected in 2H21

IND/CTA filings for ORIC-944 and ORIC-114 expected in 2H21

Cash and investments of \$305.9 million, expected to fund current operating plan into 2024

SOUTH SAN FRANCISCO and SAN DIEGO, Calif. , Aug. 10, 2021 (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 June 30, 2021.

"We executed well in the first half of the year, achieving multiple milestones, including the initial data readout for ORIC-101 in combination with nab-paclitaxel in solid tumors and the clearance of the IND application for ORIC-533, our small molecule CD73 inhibitor," said Jacob Chacko, M.D., president and chief executive officer. "In the second half of the year, we expect to present preliminary safety, pharmacokinetic, and translational data, as well as preliminary antitumor activity from our ongoing Phase 1 trial of ORIC-101 in combination with enzalutamide in prostate cancer. In addition, we look forward to dosing our first patient with ORIC-533 and to filing an IND for ORIC-944, our allosteric PRC2 inhibitor, and a CTA for ORIC-114, our brain penetrant EGFR/HER2 exon 20 inhibitor. Furthermore, the proceeds from our recent financing have bolstered our balance sheet with funding for the continued development of ORIC-101 and our other three product candidates through multiple data readouts expected in the 2022 and 2023 timeframe."

Second Quarter 2021 and Other Recent Highlights

- **Initial ORIC-101 Clinical Data Presented at ASCO:** In June 2021, ORIC presented initial clinical data from the Phase 1b trial of ORIC-101 in combination with nab-paclitaxel. The trial is a single arm, multicenter, open-label study conducted in two parts, intended to establish the recommended Phase 2 dose (RP2D), safety, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity when administered to patients with advanced or metastatic solid tumors. Following the completion of the Part I dose escalation portion of the study, the RP2D was determined to be 160 mg of ORIC-101 continuous once daily dosing in combination with 75 mg/m² of nab-paclitaxel, without requirement for prophylactic granulocyte-colony stimulating factor (G-CSF). For the Part II dose expansion portion of the study, up to 132 patients are expected to be enrolled across four cohorts, including pancreatic ductal adenocarcinoma (PDAC), ovarian cancer, triple negative breast cancer, and other advanced solid tumors. Enrollment continues in the Part II dose expansion cohorts at 12 clinical sites across the United States. Patients in the dose expansion portion of the study are required to have previously progressed on a taxane-based therapy, with retrospective analysis of GR expression and other potentially predictive biomarkers. Key findings of the initial data presented included:

Safety Analyses:

- As of March 31, 2021, a total of 31 patients were enrolled across Parts I and II of the study, which included 12 patients treated at non-RP2D doses and 19 patients treated at the RP2D. Patients treated at the RP2D were heavily pretreated, with a median of four prior therapies, and all had previously received a taxane-based therapy.
 - As of the database cutoff date of April 21, 2021, the RP2D was well tolerated; treatment-related adverse events were primarily Grade 1 or 2, with only three Grade 3 events, which all resolved with dose interruption.
 - There were no treatment-related discontinuations and no requirement for prophylactic G-CSF at the RP2D.
- **Preliminary Antitumor Activity (as of the database cutoff date of April 21, 2021):**
 - The efficacy evaluable population included a total of 23 patients who had an opportunity for at least one on-treatment tumor assessment.
 - Five partial responses were observed, one confirmed and four unconfirmed, including in heavily pretreated patients with PDAC, endometrial and breast cancers, who previously progressed on or after a taxane-based therapy.
 - Further evidence of antitumor activity was demonstrated by prolonged disease stabilization across multiple solid tumors, including PDAC, breast, gastric, esophageal, and testicular cancers.
 - Notably, three of the four efficacy evaluable patients with late-line relapsed PDAC treated at the RP2D demonstrated extended progression free survival ranging from 3.6 months to 5.3+ months in the third-line or later setting, despite having already previously progressed on nab-paclitaxel.

- **ORIC-533 IND Cleared by FDA:** In June 2021, ORIC announced that the U.S. Food and Drug Administration (FDA)

cleared its Investigational New Drug Application (IND) for ORIC-533 to proceed into a first-in-human clinical trial. ORIC-533 is a highly potent, 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. Based on a preclinical collaboration with an academic key opinion leader that generated compelling single agent activity in patient derived model systems in an undisclosed tumor type, the company plans to pursue a single agent clinical development plan in this indication. ORIC plans to initiate the Phase 1 clinical trial with ORIC-533 in the second half of 2021 to evaluate safety, PK and preliminary efficacy in cancer patients.

- **Preclinical Data Presented at AACR:** In April 2021, ORIC presented posters on four programs at the 2021 American Association for Cancer Research (AACR) virtual annual meeting.
- **Corporate:** In July 2021, ORIC raised gross proceeds of \$50.0 million through the sale of approximately 2.6 million shares under its ATM offering, with participation based on unsolicited interest received from a healthcare specialist fund. The company sold the shares at a purchase price per share of \$19.25, a premium to the market price at the time of the sale.

Anticipated Milestones

- ORIC anticipates the following milestones in the second half of 2021:
 - ORIC-101: Report interim safety, pharmacokinetics, translational data, and preliminary antitumor activity from the ongoing combination trial with enzalutamide
 - ORIC-533: Initiate Phase 1 study
 - ORIC-944: File IND
 - ORIC-114: File CTA
 - Present additional preclinical data at scientific conferences

Second Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Short-term Investments:** Cash, cash equivalents, and short-term investments totaled \$261.1 million as of June 30, 2021. Along with the July 2021 ATM offering gross proceeds of \$50.0 million, the company expects its cash, cash equivalents, and short-term investments of \$305.9 million as of July 31, 2021, will be sufficient to fund its current operating plan into 2024.
- **R&D Expenses:** Research and development expenses were \$15.5 million for the three months ended June 30, 2021, compared to \$7.7 million for the three months ended June 30, 2020, an increase of \$7.8 million. For the six months ended June 30, 2021, R&D expenses were \$27.2 million compared to \$15.0 million for the same period of 2020, an increase of \$12.2 million. The increases for the 2021 periods were primarily driven by an increase in external expenses related to the advancement of ORIC-101 and our other product candidates of \$6.4 million and \$10.0 million for the three and six months ended June 30, 2021, respectively, as well as higher personnel costs, including additional non-cash stock-based compensation of \$0.7 million and \$1.5 million for the three and six months ended June 30, 2021, as compared to the same periods in 2020, respectively.
- **G&A Expenses:** General and administrative expenses were \$5.5 million for the three months ended June 30, 2021, compared to \$3.4 million for the three months ended June 30, 2020, an increase of \$2.1 million. For the six months ended June 30, 2021, G&A expenses were \$10.4 million compared to \$5.3 million for the same period of 2020, an increase of \$5.1 million. The increases were primarily due to higher personnel costs, including additional non-cash stock-based compensation of \$1.1 million and \$2.5 million for the three months and six months ended June 30, 2021, as compared to the same periods in 2020, respectively, as well as higher professional services and related costs to operate as a public company.

About ORIC Pharmaceuticals, Inc.

ORIC Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to improving patients' lives by *Overcoming Resistance In Cancer*. ORIC's lead product candidate, ORIC-101, is a potent and selective small molecule antagonist of the glucocorticoid receptor, which has been linked to resistance to multiple classes of cancer therapeutics across a variety of solid tumors. ORIC-101 is currently in two separate Phase 1b trials in combination with (1) Abraxane (nab-paclitaxel) in advanced or metastatic solid tumors and (2) Xtandi (enzalutamide) in metastatic prostate cancer. ORIC's other 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, (2) ORIC-944, an allosteric inhibitor of the polycomb repressive complex 2 (PRC2) via the EED subunit, being developed for prostate cancer, and (3) 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. 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-101 and ORIC-533 clinical trials and development; the expected timing of reporting interim data from the ORIC-101 clinical trials; plans underlying ORIC-944, ORIC-114 or any other programs; the planned IND filing for ORIC-944 and CTA filing for ORIC-114; ORIC's anticipated 2021 milestones; the expected timing of data readouts; the period over which ORIC estimates its existing cash, cash equivalents and short-term investments will be sufficient to fund its current operating plan; and statements by the company's president 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-101, ORIC-533, ORIC-944, ORIC-114 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 10, 2021, 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 261,068	\$ 293,600
Prepaid expenses and other current assets	3,884	3,097
Total current assets	264,952	296,697
Property and equipment, net	1,828	1,981
Other assets	1,447	319
Total assets	\$ 268,227	\$ 298,997
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 838	\$ 757
Accrued liabilities	9,066	8,245
Total current liabilities	9,904	9,002
Other long-term liabilities	—	219
Total liabilities	9,904	9,221
Total stockholders' equity	258,323	289,776
Total liabilities and stockholders' equity	\$ 268,227	\$ 298,997

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

(in thousands, except share and per share amounts)

Three Months Ended		Six Months Ended	
June 30,		June 30,	
2021	2020	2021	2020

Operating expenses:				
Research and development	\$ 15,517	\$ 7,723	\$ 27,214	\$ 14,977
General and administrative	5,540	3,400	10,396	5,325
Total operating expenses	<u>21,057</u>	<u>11,123</u>	<u>37,610</u>	<u>20,302</u>
Loss from operations	(21,057)	(11,123)	(37,610)	(20,302)
Other income:				
Interest income, net	33	25	77	266
Other income	15	74	15	140
Total other income	<u>48</u>	<u>99</u>	<u>92</u>	<u>406</u>
Net loss	<u>\$ (21,009)</u>	<u>\$ (11,024)</u>	<u>\$ (37,518)</u>	<u>\$ (19,896)</u>
Other comprehensive gain (loss):				
Unrealized (loss) gain on available-for-sale securities	(14)	—	34	—
Comprehensive loss	<u>\$ (21,023)</u>	<u>\$ (11,024)</u>	<u>\$ (37,484)</u>	<u>\$ (19,896)</u>
Net loss per share, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (0.51)</u>	<u>\$ (1.02)</u>	<u>\$ (1.68)</u>
Weighted-average shares outstanding, basic and diluted	<u>36,701,836</u>	<u>21,627,361</u>	<u>36,690,824</u>	<u>11,808,103</u>