ORIC Pharmaceuticals Reports Third Quarter 2021 Financial Results and Operational Update

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Initial clinical data from Phase 1b trial of ORIC-101 in combination with enzalutamide and preclinical data on ORIC-114 presented at AACR-NCI-EORTC

Update on oral CD73 inhibitor program to be presented at the American Society of Hematology (ASH) Annual Meeting and Phase 1 trial initiation of single agent ORIC-533 in patients with multiple myeloma expected in 4Q 2021

CTA filing submitted for ORIC-114 and IND filing for ORIC-944 expected in 4Q 2021

Strengthened board of directors with addition of Steven L. Hoerter

Cash and investments of $296.5 million expected to fund current operating plan into 2024

SOUTH SAN FRANCISCO, Calif. and SAN DIEGO, Nov. 08, 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 September 30, 2021.

“We are proud of the ongoing steady advancement of our broad pipeline” said Jacob Chacko, M.D., president and chief executive officer. “In October, we announced initial trial data from our ORIC-101 combination with enzalutamide in prostate cancer, which demonstrated a safe and tolerable profile and encouraging early antitumor activity in a key patient population; in November, we submitted a CTA filing for ORIC-114, our brain penetrant EGFR/HER2 exon 20 inhibitor. In the fourth quarter, we also expect to initiate a Phase 1 trial with our CD73 inhibitor ORIC-533 as a single agent in multiple myeloma and to file an IND for ORIC-944, our allosteric PRC2 inhibitor.”

Third Quarter 2021 and Other Recent Highlights

- **Data Presentations at AACR-NCI-EORTC:**

  ORIC-101: The Phase 1b clinical trial of ORIC-101 in combination with enzalutamide 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 of the combination when administered in patients with metastatic prostate cancer progressing on enzalutamide. Following the completion of the Part I dose escalation portion of the trial, the RP2D was determined to be 240 mg of ORIC-101 and 160 mg of enzalutamide once daily. In the Part II dose expansion portion of the trial, up to 48 patients with metastatic prostate cancer progressing on enzalutamide are expected to be enrolled and treated with the combination at the RP2D. Patients are enrolled independent of GR status, with retrospective analysis of AR variants and GR expression and other potentially predictive biomarkers. Enrollment continues in the Part II dose expansion cohorts at nine clinical sites across the United States.

  As of the August 20, 2021, data cut-off date, the key findings of the initial data presented included:

  Preliminary Safety Analyses:

  - 25 patients were enrolled across Parts I/II of the study, which included 7 patients treated at non-RP2D doses and 18 patients treated at the RP2D.
  - RP2D was well tolerated; treatment-related adverse events were primarily Grade 1 or 2, with only four Grade 3 events, which all resolved with dose interruption.
  - Tolerability profile for the combination was generally consistent with that of single agent enzalutamide.

  Preliminary PK and Biomarker Analyses:

  - Plasma concentrations exceeded the threshold for GR inhibition at all dose levels, with GR target gene suppression observed after one dose of ORIC-101 in peripheral blood mononuclear cells from 22 of 23 patients.
  - ORIC-101 exposure increased with dose.
  - No evidence observed of drug-drug interaction impacting enzalutamide levels.
  - Translational efforts identified a key patient population, in line with published literature, consisting of the ~60% of patients with tumors lacking biomarkers of AR resistance (e.g., ARv7 splice variant, AR L702H point mutation) and AR independence (e.g., lineage switching).

  Preliminary Antitumor Activity:

- Within the key patient population (n=8), 75% (6 of 8) of patients' tumors expressed moderate to high GR and 25% (2 of 8) of patients' tumors expressed low GR.
- The two patients with low GR came off treatment at less than two months. In contrast, the six patients with moderate to high GR demonstrated prolonged time on treatment (with two patients on treatment for over seven months, and another four patients still ongoing at varying durations at the time of the data cut).

ORIC-114: A brain penetrant, orally bioavailable, irreversible inhibitor designed to selectively target EGFR and HER2 with high potency against exon 20 insertion mutations. Key findings of the preclinical presentation included:

- ORIC-114 demonstrated greater cell potency on HER2-positive breast cancer cell lines relative to non-amplified cell lines and was more potent than lapatinib and tucatinib, two approved tyrosine kinase inhibitors for the treatment of HER2-positive breast cancer.
- ORIC-114 demonstrated robust tumor regressions in a HER2-positive breast cancer in vivo model without significant body weight loss.
- ORIC-114 demonstrated superior brain exposure compared to other EGFR exon 20 and HER2 targeted agents.

- **Corporate:** In August 2021, the company appointed Steven L. Hoerter to its board of directors. Mr. Hoerter is currently CEO of Deciphera Pharmaceuticals and has more than twenty-five years of experience in sales, marketing, commercial and public company leadership roles.

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 fourth quarter of 2021:
  - ORIC-533:
    - Present update on oral CD73 inhibitor program at the ASH Annual Meeting
    - Initiate single agent Phase 1 trial in patients with multiple myeloma
  - ORIC-944: File IND

Third Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Investments:** As of September 30, 2021, cash, cash equivalents, and investments totaled $296.5 million, which the company expects will fund its current operating plan into 2024.

- **R&D Expenses:** Research and development expenses were $12.9 million for the three months ended September 30, 2021, compared to $8.8 million for the three months ended September 30, 2020, an increase of $4.1 million. For the nine months ended September 30, 2021, R&D expenses were $40.1 million compared to $23.8 million for the same period of 2020, an increase of $16.3 million. The increases for the 2021 periods were primarily driven by an increase in external expenses related to the advancement of ORIC-101 and other product candidates of $2.8 million and $12.8 million for the three and nine months ended September 30, 2021, respectively, as well as higher personnel costs, including additional non-cash stock-based compensation of $0.7 million and $2.2 million for the three and nine months ended September 30, 2021, as compared to the same periods in 2020, respectively.

- **G&A Expenses:** General and administrative expenses were $5.6 million for the three months ended September 30, 2021, compared to $3.8 million for the three months ended September 30, 2020, an increase of $1.8 million. For the nine months ended September 30, 2021, G&A expenses were $16.0 million compared to $9.1 million for the same period of 2020, an increase of $6.8 million. The increases were primarily due to higher personnel costs, including additional non-cash stock-based compensation of $1.1 million and $3.6 million for the three months and nine months ended September 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, being developed for multiple myeloma, (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, including expectations regarding patient enrollment and the expected timing of initiating a Phase 1 clinical trial of ORIC-533; plans underlying ORIC-944, ORIC-114 or any other programs and the planned IND filing for ORIC-944; ORIC's anticipated fourth quarter 2021 milestones; the period over which ORIC estimates its existing cash, cash equivalents and available-for-sale 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, initial, 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 November 8, 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)

	September 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 289,519	$ 293,600
Prepaid expenses and other current assets	3,330	3,097
Total current assets	292,849	296,697
Investments, available-for-sale	6,956	—
Property and equipment, net	1,825	1,981
Other assets	12,550	319
Total assets	$ 314,180	$ 298,997
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 419	$ 757
Accrued liabilities	11,484	8,245
Total current liabilities	11,903	9,002
Other long-term liabilities	10,741	219
Total liabilities	22,644	9,221
Total stockholders' equity	291,536	289,776
Total liabilities and stockholders' equity	$ 314,180	$ 298,997

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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 12,899	$ 8,831	$ 40,113	$ 23,808
Acquired in-process research and development	—	12,971	—	12,971
General and administrative	5,557	3,800	15,953	9,125
Total operating expenses	18,456	25,602	56,066	45,904
Loss from operations	(18,456)	(25,602)	(56,066)	(45,904)
Other income:				
Interest income, net	30	10	107	276
Other income	—	44	15	184
Total other income	30	54	122	460
Net loss	$ (18,426)	$ (25,548)	$ (55,944)	$ (45,444)
Other comprehensive gain (loss):				
Unrealized (loss) gain on available-for-sale investments	(5)	(29)	29	(29)
Comprehensive loss	$ (18,431)	$ (25,577)	$ (55,915)	$ (45,473)
Net loss per share, basic and diluted	$ (0.47)	$ (0.84)	$ (1.49)	$ (2.52)
Weighted-average shares outstanding, basic and diluted	39,008,114	30,314,904	37,471,740	18,022,068