

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported) **June 28, 2021**

**ORIC Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39269**  
(Commission  
File Number)

**47-1787157**  
(IRS Employer  
Identification No.)

**240 E. Grand Ave, 2nd Floor**  
**South San Francisco, CA 94080**  
(Address of principal executive offices, including zip code)

**(650) 388-5600**  
(Registrant's telephone number, including area code)

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	ORIC	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events.**

On June 28, 2021, ORIC Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration provided clearance of the Company’s Investigational New Drug Application for ORIC-533, the Company’s orally bioavailable small molecule inhibitor of CD73.

The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated June 28, 2021.</a>
104	Cover Page Interactive Data File (formatted as Inline XBRL).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ORIC PHARMACEUTICALS, INC.**

Date: July 8, 2021

By: /s/ Dominic Piscitelli  
Dominic Piscitelli  
Chief Financial Officer



**ORIC Pharmaceuticals Announces FDA Clearance of IND Application for ORIC-533, a Highly Potent, Orally Bioavailable Small Molecule CD73 Inhibitor**

*ORIC expects to initiate single agent clinical trial in an undisclosed tumor type in 2H21*

*ORIC-533 IND filing is the first of three IND/CTA filings expected in 2021*

**SOUTH SAN FRANCISCO and SAN DIEGO, CA – June 28, 2021** – ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), a clinical stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company’s 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.

“The FDA clearance of our IND application for ORIC-533 is a significant milestone for ORIC as we move into the clinic with a second novel, internally discovered oncology drug candidate,” said Jacob Chacko, M.D., president and chief executive officer. “In preclinical studies, ORIC-533 has demonstrated higher potency within a high AMP environment compared to all CD73 and adenosine receptor inhibitors against which it was compared. Furthermore, in addition to the potential best-in-class properties of ORIC-533, we are excited about its differentiated clinical development plan that will explore its single agent activity in contrast to the combination studies that dominate the CD73 field today.”

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.

This is the first of three planned IND/CTA filings for 2021, with the IND filing for ORIC-944 and CTA filing for ORIC-114 expected in the second half of the year.

**About ORIC-533**

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. ORIC-533 has demonstrated greater potency in preclinical studies compared to an antibody approach, other small molecule CD73 inhibitors and inhibitors of adenosine receptors. Preclinical data suggest ORIC-533 binds CD73 with high

affinity and effectively blocks adenosine-driven immunosuppression in a high AMP environment. In preclinical studies, nanomolar concentrations of ORIC-533 efficiently rescued cytotoxic T-cell function in the presence of high AMP concentrations, reflective of AMP levels observed in tumors.

#### **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](http://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 the clinical development of ORIC-533 in an undisclosed tumor type and its potential best-in-class nature; the expected timing of initiation of the Phase 1 clinical trial of ORIC-533; the expected timing of an IND filing for ORIC-944 and a CTA filing for ORIC-114; the potential benefits of ORIC-533 or the company's other product candidates; 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-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 May 6, 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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**Investor Contact:**

Dominic Piscitelli, Chief Financial Officer  
dominic.piscitelli@oricpharma.com  
[info@oricpharma.com](mailto:info@oricpharma.com)