
**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): July 16, 2020

Intercept Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35668
(Commission
File Number)

22-3868459
(IRS Employer
Identification No.)

10 Hudson Yards, 37th Floor
New York, NY 10001
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(646) 747-1000**

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:

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ICPT	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 July 16, 2020, Intercept Pharmaceuticals, Inc. (the “Company”) received a paragraph IV certification notice (the “PIV Notice”) from Lupin Limited (“Lupin”) indicating that Lupin has submitted to the U.S. Food and Drug Administration an Abbreviated New Drug Application (“ANDA”) seeking approval to manufacture and sell a generic version of the Company’s 5 mg and 10 mg dosage strengths of Ocaliva[®] (obeticholic acid) for primary biliary cholangitis prior to the expiration of the Company’s U.S. Patents Nos. 7,138,390, 9,238,673, 10,047,117, 10,052,337, and 10,174,073 (collectively, the “Challenged Patents”), which are listed for Ocaliva in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the “Orange Book”). The PIV Notice alleges that the Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in Lupin’s ANDA. Lupin did not make a paragraph IV certification against the Company’s U.S. Patents Nos. 8,058,267 or 8,377,916, which are also listed for Ocaliva in the Orange Book. The Company is currently reviewing the PIV Notice from Lupin and intends to vigorously defend and enforce its intellectual property rights protecting Ocaliva.

The Company plans to update investors on any additional paragraph IV certification notices that it may receive from ANDA filers seeking approval of a generic version of Ocaliva in its Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K filed with the Securities and Exchange Commission.

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements regarding the Company’s intention to defend and enforce its intellectual property rights as well as Intercept’s understanding of the content of the paragraph IV certification notice. These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by the Company’s management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. Actual results may differ materially from historical results or those anticipated or predicted by the Company’s forward-looking statements as a result of various important factors, including, but not limited to, the impact of general economic, industry, market or political conditions and the other risks and uncertainties identified in the Company’s periodic filings, including the Company’s Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Report on Form 10-Q for the month ended March 31, 2020.

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.

INTERCEPT PHARMACEUTICALS, INC.

By: /s/ Sandip Kapadia

Name: Sandip Kapadia

Title: Chief Financial Officer and Treasurer

Date: July 17, 2020
