

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 22, 2023

Intercept Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35668	22-3868459
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

305 Madison Avenue, Morristown, NJ 07960
(Address of principal executive offices) (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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 7.01 Regulation FD Disclosure.

On June 22, 2023, Intercept Pharmaceuticals, Inc. issued a press release, which is attached hereto as Exhibit 99.1 and is incorporated by reference, announcing receipt of a Complete Response Letter (“CRL”) from the U.S. Food and Drug Administration (“FDA”) in regard to its New Drug Application (“NDA”) for obeticholic acid (“OCA”) for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (“NASH”).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

The information in Item 7.01 and Exhibit 99.1 is being furnished, not filed.

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/ Jerome Durso

Name: Jerome Durso

Title: President and CEO

Date: June 22, 2023



Intercept Receives Complete Response Letter from FDA for Obeticholic Acid as a Treatment for Pre-Cirrhotic Fibrosis due to NASH

- *Company to discontinue all NASH-related investment and restructure the Company's operations to strengthen its focus on rare and serious liver diseases*
- *Company anticipates achieving profitability in 2024 as a result of planned actions*
- *Conference call scheduled for Friday, June 23, 2023, at 8:30 a.m. ET*

MORRISTOWN, N.J., June 22, 2023 – Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare and serious liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) in response to the Company's New Drug Application (NDA) for obeticholic acid (OCA) for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (NASH).

The FDA indicated in the CRL that it has completed its review of the NDA and determined that it cannot be approved in its present form. Based on the content of the CRL, any resubmission of an NDA for OCA in NASH would require, at a minimum, successful completion of the long-term outcomes phase of the REGENERATE study. As a result of the CRL, Intercept has decided to discontinue all NASH-related investment, restructure the Company's operations to strengthen its focus on rare and serious liver diseases, and drive an accelerated path to profitability beginning in 2024.

"While this is clearly not the outcome that we have worked toward, I'm proud of the impact that Intercept has made to move the science of NASH forward and bring the field closer to a treatment option," said Jerry Durso, President and Chief Executive Officer of Intercept. "Intercept thanks the scientists, clinicians and patients whose contributions to the clinical development of OCA in NASH have significantly advanced the understanding of this deadly disease."

Durso continued, "We believe that taking decisive action to reshape Intercept will improve our long-term ability to grow our business, innovate for patients, and create value for shareholders. We remain committed to the liver community and will continue to advance our leadership in rare and serious liver diseases where Intercept has deep expertise and a recognized dedication to therapeutic innovation."

Conference Call on Friday, June 23, 2023, at 8:30 a.m. ET

The Company will host a conference call on Friday, June 23, 2023, at 8:30 a.m. ET to address the restructuring and provide updated financial guidance. The conference call will be available via a listen-only webcast on the investor page of the Company's website at <http://ir.interceptpharma.com>. Participants who wish to ask a question may register [here](#) to receive dial-in numbers and a unique pin to join the call. A replay of the call will be available on the Intercept website shortly following the completion of the call and will be available for one year.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare and serious liver diseases, including primary biliary cholangitis (PBC) and severe alcohol-associated hepatitis (sAH). For more information, please visit www.interceptpharma.com or connect with the Company on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

This news release contains forward-looking statements (“FLS”), including regarding a planned corporate restructuring, corporate strategy and priorities, corporate financial performance and profitability, and timing of profitability. Important factors could cause actual results to differ materially from the FLS. For example, we may be less effective than expected in implementing strategic changes, restructuring and clinical trial wind-down may be slower and have greater costs than expected, and we may fail to achieve profitability due to lower revenues or higher expenses than expected.

Contacts

For more information about Intercept, please contact:

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