

INTERCEPT PHARMACEUTICALS INC
Form 8-K
July 31, 2017

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 31, 2017

INTERCEPT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-35668	22-3868459
(state or other jurisdiction	(Commission	(I.R.S. Employer
of incorporation)	File Number)	Identification No.)
10 Hudson Yards, Floor 37		10001
New York, New York		
(Address of principal executive offices)		(Zip Code)

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

(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))

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 2.02 Results of Operations and Financial Condition.

On July 31, 2017, Intercept Pharmaceuticals, Inc. (the “Company”) announced its financial results for the three and six months ended June 30, 2017 and provided other general business updates. A copy of the Company’s press release (the “Press Release”) containing such announcement is attached hereto as Exhibit 99.1. The information in the Press Release is incorporated by reference into this Item 2.02 of this Current Report on Form 8-K.

Except as shall be expressly set forth by specific reference, the information contained or incorporated by reference in this Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Bifurcation of Role of David Shapiro, M.D.

On July 31, 2017, the Company announced that the role of David Shapiro, M.D., the Company’s Chief Medical Officer and Executive Vice President, Development, will be bifurcated into two separate roles. Dr. Shapiro will remain with the Company and continue to serve as its Chief Medical Officer. Until the Company has filled the position of head of research and development, Dr. Shapiro will continue to lead the Company’s research and development organization.

Item 7.01. Regulation FD Disclosure.

On July 31, 2017, the Company announced top-line results from the Phase 2 AESOP trial in primary sclerosing cholangitis (“PSC”) which evaluated the effects of 24 weeks of treatment with varying doses of obeticholic acid (“OCA”) compared to placebo. This trial achieved its primary endpoint, which the Company believes establishes a proof-of-concept of OCA in a second cholestatic liver disease. The press release is attached hereto as Exhibit 99.2.

On July 31, 2017, the Company announced top-line results from the CONTROL trial which characterized the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in nonalcoholic

steatohepatitis patients. This trial achieved its primary endpoint. The press release is attached hereto as Exhibit 99.3.

Except as shall be expressly set forth by specific reference, the information contained or incorporated by reference in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit 99.1 Press Release of Intercept Pharmaceuticals, Inc. on financial results dated July 31, 2017

Exhibit 99.2 Press Release of Intercept Pharmaceuticals, Inc. on AESOP trial dated July 31, 2017

Exhibit 99.2 Press Release of Intercept Pharmaceuticals, Inc. on CONTROL trial dated July 31, 2017

SIGNATURE

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.

Dated: July 31, 2017 /s/ Mark Pruzanski
Mark Pruzanski, M.D.

President and Chief Executive Officer