

INTERCEPT PHARMACEUTICALS INC

Form 8-K

August 18, 2016

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): August 12, 2016

INTERCEPT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction

001-35668 22-3868459
(Commission (I.R.S. Employer

of incorporation)

File Number) Identification No.)

450 W. 15th Street, Suite 505

10011

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)

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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))

Item 1.01 Entry into a Material Definitive Agreement.

On August 12, 2016 (“Effective Date”), Intercept Pharma Europe Ltd. (“IPEL”), a wholly-owned subsidiary of Intercept Pharmaceuticals, Inc. (“Intercept”), and PharmaZell GMBH (“PharmaZell”) entered into a Commercial Manufacturing and Supply Agreement (the “Agreement”).

Pursuant to the Agreement, PharmaZell has agreed to manufacture and supply to IPEL and IPEL has agreed to purchase from PharmaZell a certain percentage of IPEL’s commercial requirements of active pharmaceutical ingredient (“API”) for use in Ocaliva[®] (obeticholic acid). In addition, subject to certain regulatory events, IPEL has agreed to purchase a specified minimum quantity of API for delivery in 2017 and 2018. Subject to IPEL’s purchase obligations under the Agreement, IPEL has the right to enter into arrangements with one or more alternate sources for the commercial supply of API. The Agreement provides for pricing for API structured on a tiered basis, with the price reduced as the volume of API ordered increases.

The Agreement has an initial term that runs from the Effective Date until December 31, 2020, and is subject to two-year automatic renewal terms, unless either party provides notice of non-renewal at least 12 months prior to the end of the initial term or then-current renewal term. IPEL may terminate the Agreement immediately with written notice upon the occurrence of certain regulatory events, or PharmaZell’s failure to meet certain quality standards, applicable laws or specified delivery obligations. Each party also has the right to terminate the Agreement immediately upon written notice for other customary reasons such as material breach and bankruptcy.

The Agreement contains provisions relating to compliance by PharmaZell with current Good Manufacturing Practices and applicable laws, indemnification, confidentiality, intellectual property, dispute resolution and other customary matters for an agreement of this kind. Certain provisions of the Agreement are subject to a quality agreement previously entered into by the parties. Intercept has agreed to guarantee IPEL’s financial obligations under the Agreement.

Intercept expects to file the Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2016. The foregoing description is qualified in its entirety by reference to the complete text of the Agreement when filed.

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: August 18, 2016 /s/ Mark Pruzanski
Mark Pruzanski, M.D.

President and Chief Executive Officer