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): May 15, 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 1.01 Entry into a Material Definitive Agreement.

On May 15, 2023, Intercept Pharma Europe Ltd. ("IPEL"), a wholly owned subsidiary of registrant Intercept Pharmaceuticals, Inc. (the "Company"), entered into an Amendment (the "Amendment") to the Agreement for the Supply of Manufactured Products (the "Supply Agreement") dated May 5, 2022 between IPEL and Amdipharm Ltd. ("Amdipharm"), an affiliate of Advanz Pharma (together with its affiliates, "Advanz"). In 2022, Advanz bought the Company's ex-U.S. commercial operations, sublicensed the right to commercialize obeticholic acid ("OCA") for primary biliary cholangitis ("PBC") and (if approved) nonalcoholic steatohepatitis ("NASH") outside of the United States, and contracted with IPEL to supply Amdipharm with OCA tablets for PBC and (if approved) NASH.

The Amendment clarifies and elaborates definitions pertaining to OCA products for PBC and NASH, including expected tablet sizes and calculation of demonstrable costs of manufacture, and updates timing and procedures for sale of 25 mg tablets of OCA for NASH from IPEL to Amdipharm.

Furthermore, the Amendment provides that Amdipharm and Advanz may not use any product purchased under the Supply Agreement for an early access program, expanded access program, authorization for temporary use program, or similar program (each, an "EAP"), without specific prior written approval by the Company. However, following the execution of the agreement described in Item 8.01 below, Amdipharm may engage in an EAP in France for OCA for NASH without further approval from the Company.

The Amendment is attached as Exhibit 10.1 and incorporated herein by reference. This description of the Amendment is not complete, and is qualified by reference to the text of the Amendment.

Item 8.01 Other Events.

On May 15, 2023, the Company agreed with Advanz affiliates Mercury Pharma Group Limited ("Mercury") and Advanz Pharma France SAS ("Advanz France") to settle and have "finally resolved" the responsibility of the Company for the liability of Advanz France to the French government for payback of past amounts received for product sales. Under the Share Purchase Agreement (the "SPA") dated May 5, 2022 between the Company and Mercury, the Company sold ownership of Advanz France (formerly known as Intercept Pharma France SAS) to Mercury, while the Company retained responsibility to Advanz for the cost of this liability to the French government. Pursuant to clause 14.2 of the SPA, Mercury will pay the Company approximately $74,000, representing the approximate dollar equivalent of the difference of approximately €67,000 between the liability estimated in the SPA (€40,600,000) and the actual liability agreed between the parties (approximately €40,533,000).

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit Number	Description
10.1	Amendment to the Agreement for the Supply of Manufactured Products, dated May 15, 2023, between Intercept Pharma Europe Ltd. and Amdipharm Ltd.
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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/ Rocco Venezia
Name: Rocco Venezia
Title: Chief Accounting Officer

Date: May 17, 2023

Exhibit 10.1

Execution Version

AMENDMENT TO THE AGREEMENT FOR THE SUPPLY
OF
MANUFACTURED PRODUCTS

This Amendment Agreement ("**Amendment**") is made the 15th day of May, 2023 ("**Amendment Date**") and is an amendment to the Agreement for the Supply of Manufactured Products made on May 5, 2022 ("**Original MSA**") by and between **INTERCEPT PHARMA EUROPE LTD.**, a company incorporated and registered in England and Wales with company number 09224395 whose registered office is at One, Glass Wharf, Bristol, BS2 0ZX ("**Supplier**") and **AMDIPHARM LTD**, a company organized and existing under the laws of Ireland, having its registered office at 3, Burlington Road, Dublin 4, Ireland, and having its trading address at Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland ("**Purchaser**").

NOW, THEREFORE, in consideration of the rights and obligations contained herein, and for other good and valuable consideration, the adequacy of which is hereby acknowledged, the Parties hereby agree as follows:

1. For purposes of this Amendment, the terms defined in the Original MSA have the same meanings when used in this Amendment unless specifically indicated otherwise.

2. Clause 1.1 of the Original MSA is amended by:

2.1 inserting the following definitions (following the alphabetical nature of the list in clause 1):

"Amendment" *means the amendment to the Agreement dated as of the Amendment Date.*

*"**Amendment Date**" means May 15th, 2023.*

*"**CEPS Letter**" means the letter dated as of the date hereof from Mercury Pharma Group Limited ("**MPGL**") and Advanz Pharma France SAS to Intercept Pharmaceuticals, Inc. regarding the resolution and repayment of the liability of the former Intercept Pharma France SAS to the French government relating to historical sales of PBC Product.*

*"**EMA**" means the European Medicines Agency.*

*"**HC**" means Health Canada.*

*"**Marketing Approval(s)**" mean all approvals and permissions (excluding reimbursement approvals) from the Regulatory Authorities in the Territory (as defined in the Sub-License Agreement) (or parts of the Territory) that are necessary for the importation or manufacturing (if applicable) of the Products and their distribution, use, marketing, and sale in the Territory (or parts of the Territory).*

*"**MHRA UK**" means the Medicines and Healthcare products Regulatory Agency.*

*"**PBC Product**" means the Products that contain OCA as the sole API for the treatment of PBC, in general expected to be the 5mg and 10mg Products.*

*"**PBC**" means primary biliary cholangitis.*

*"**Initial NASH POs**" means both the First NASH PO and the Second NASH PO and "Initial NASH PO" shall mean one or other of them as applicable.*

*"**Joint Steering Committee**" or "**JSC**" means the steering committee described in that certain sublicence agreement, dated May 5, 2022, by and between Supplier and MPGL, as amended from time to time.*

2.2 replacing the existing definitions of 'Demonstrable Costs of Manufacture', 'Minimum Order Quantity', 'NASH Product' and 'Product' with the following definitions:

*"**Demonstrable Costs of Manufacture**" means the costs incurred by the Supplier in procuring the Manufacture of the Products, including, without limitation, third-party manufacturing costs, including (without limitation) costs incurred in purchasing API, tableting, and release testing (estimations of which as at the Effective Date are as set out in Schedule 1); provided, however, notwithstanding any of the foregoing; (i) during the first five (5) years after the Completion, no costs incurred in purchasing API for PBC Products shall be included in the Demonstrable Costs of Manufacture; and (ii) for the First NASH PO only, Demonstrable Costs of Manufacture shall include 50% of the costs incurred for purchasing API and 100% of the costs incurred for tableting and testing unless and until the remaining 50% of costs for API are payable pursuant to clause 4.5.1.*

*"**Minimum Order Quantity**" means the minimum quantity of a type of Product (being 5mg, 10mg, or 25mg) that may be ordered by the Purchaser in each Purchase Order, being one Batch per Product type.*

*"**NASH Products**" means the Products that contain OCA as the sole API for the treatment of NASH, in general expected to be the 25mg Products.*

*"**Products**" means the PBC Products and NASH Products, being the products (i.e. tablets) set out in Schedule 1: Products and, where the context requires, the particular Products ordered by and supplied to the Purchaser.*

3. Clause 3 of the Original MSA is amended by inserting the following provision:

3.10 For the avoidance of doubt, each Forecast provided by the Purchaser shall be split by Product type (i.e. 5mg, 10mg, or 25mg and whether the Product is a PBC Product or NASH Product).

4. Clause 4 of the Original MSA is amended by:

4.1 inserting a new sub-clause 4.5 as follows:

4.5 Notwithstanding any conflicting provision in this Agreement or elsewhere:

*4.5.1 The initial Purchase Order placed by Purchaser to Supplier for 25 mg NASH Product ("**First NASH PO**") shall: (a) be submitted by Purchaser to Supplier within 90 calendar days following the Amendment Date, (b) be for one Batch only, (c) subject to compliance with clause 4.4 and this clause 4.5.1, be immediately accepted by the Supplier on receipt of payment in full and cleared funds of the amount invoiced by the Supplier in accordance with clause 12.6, at which point the Purchase Order shall become binding on the parties, and (d) be made available for delivery to Purchaser within 180 calendar days from the date the Supplier was deemed to have accepted the First NASH PO in accordance with this clause.*

For the First NASH PO, 50% of the costs incurred for purchasing API and 100% of the costs incurred for tableting and testing shall be paid upfront as provided herein. The remaining 50% of the costs for API shall be payable if the Purchaser obtains Marketing Approval(s) from at least one of EMA, HC, or MHRA UK. If payable, such costs shall be paid promptly following such Marketing Approval. However, by December 31, 2024, Purchaser shall pay Supplier the remaining 50% of costs for API if no EMA, HC, or MHRA UK Marketing Approvals have been obtained by December 31, 2024, but also none of EMA, HC, and MHRA UK have yet rejected the NASH Product.

*4.5.2 The second Purchase Order placed by Purchaser to Supplier for 25 mg NASH Product ("**Second NASH PO**") shall, notwithstanding any prior Forecast submitted by the Purchaser to the Supplier: (a) be submitted by Purchaser to Supplier within 90 calendar days following receipt of all of the necessary Regulatory Approvals necessary to sell, market and distribute the NASH Product in the United States market, (b) be for up to two (2) Batches only, (c) strictly subject to compliance with clause 4.4 and this clause 4.5.2, be immediately accepted by the Supplier on receipt of payment in full and cleared funds of the amount invoiced by the Supplier in accordance with clause 12.6, at which point the Purchase Order shall become binding on the parties, and (d) be made available for delivery to Purchaser within 180 calendar days from the date the Supplier was deemed to have accepted the Second NASH PO in accordance with this clause.*

5 Clause 5 is amended by inserting the following new clause 5.13:

*5.13 Notwithstanding the last sentence of clause 5.10, the Purchaser shall not, and shall direct its Group Companies not to, and represents and warrants that its Group Companies shall not, use any Products purchased under this Agreement for or in connection with any early access programs, expanded access programs, authorisation for temporary use programs, or similar ("**EAPs**"), without the specific prior written approval of the Supplier; provided, however, that notwithstanding any of the foregoing, following the execution of the Amendment and the CEPS Letter: (i) the Purchaser may engage in the Early Access Program (Accès Précoce) program in France (the "**France EAP**") in its discretion, and Purchaser's participation in such program shall not require the Supplier's or its Group Companies' or the JSC's further approval or consent; and (ii) Supplier shall supply the Product ordered by Purchaser for use with the France EAP pursuant to the provisions elsewhere herein.*

6 Clause 12 of the Original MSA shall be amended by inserting the following clauses:

12.6 Clauses 12.1 and 12.2 shall not apply to the Initial NASH POs. Instead, the Supplier shall invoice in respect of each Initial NASH PO within five (5) days of its receipt of each Initial NASH PO and the Purchaser shall pay such invoices immediately.

12.7 For the avoidance of doubt and notwithstanding anything to the contrary in this Agreement, except as specifically provided in clause 1.1 'Demonstrable Costs of Manufacture', the purchase of Products prior to Regulatory Approval shall be entirely at the Purchaser's risk. The Purchaser shall be obliged to pay the invoices raised in accordance with this Agreement notwithstanding any action by a Regulatory Authority, including any requirement for changes to Product specification after the point at which the Purchaser submits a Purchase Order to the Supplier.

7 For the avoidance of doubt, clause 16.7 of the Original MSA (and in particular clause 16.7.5 of the Original MSA) shall continue to apply to the arrangements as modified by this Amendment and the supply of all Products, including NASH Products.

8 Schedule 1 of the Original MSA is amended by:

7.1 deleting the following paragraph:
"****Supply of NASH Product 25mg tablets only available following Regulatory Approval of the NASH Product in the Territory (as defined in the Sub-License Agreement).*"

7.2 adding at the end of the double asterisks paragraph the following:

"*For the avoidance of doubt, other than as specifically provided herein, nothing shall prevent the Supplier charging the Purchaser its actual Demonstrable Costs of Manufacture incurred from time to time, in accordance with the terms of this Agreement*."

8 Except as expressly amended by this Amendment, the Original MSA shall remain in full force and effect as the same was in effect immediately prior to the date of this Amendment.

9 To the extent of any conflict between the terms of the Original MSA and this Amendment, the terms of this Amendment will prevail.

10 This Amendment and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation is governed by and construed in accordance with, the law of England and Wales.

11 Clause 27 of the Original MSA shall apply to this Amendment as if set out in full within this Amendment. Subject to clause 27 of the Original MSA, as incorporated into this Amendment, each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this Amendment or its subject matter or formation.

[The remainder of this page is intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Amendment effective as of the date first written above by their respective officers thereunto duly authorized.

For an on behalf of **INTERCEPT PHARMA EUROPE LIMITED**

/s/ Stephanie Kenyon

by: Stephanie Kenyon
Sr. Director

For an on behalf of **AMDIPHARM LIMITED**

/s/ Andreas Stickler

by: Andreas Stickler
Director