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): **September 29, 2020**

COLLEGIUM PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Virginia	**001-37372**	**03-0416362**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(IRS Employer Identification No.)

100 Technology Center Drive
Suite 300
Stoughton, MA 02072
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(781) 713-3699**

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	COLL	The NASDAQ Global Select Market

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 1.01 Entry into a Material Definitive Agreement.

On September 30, 2020, Collegium Pharmaceutical, Inc. (the "**Company**") announced that it reached a settlement with Teva Pharmaceuticals USA, Inc. ("**Teva**") resolving the patent litigation in the U.S. District Court for the District of Delaware. The Company brought this litigation in response to Teva's filing of an Abbreviated New Drug Application, which sought approval to market a generic version of Xtampza ER prior to the expiration of the Company's applicable patents.

Pursuant to the terms of the settlement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company will grant Teva a license to market its generic version of Xtampza ER in the United States beginning on or after September 2, 2033 (subject to U.S. Food and Drug Administration approval, and acceleration under certain circumstances). As a result of the settlement, Teva has agreed to a consent judgment confirming that its proposed generic products infringe upon the Company's asserted patents and that those patents are valid and enforceable with respect to Teva's proposed generic products. Additional details regarding the settlement are confidential.

The foregoing description of the settlement agreement and the license Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreements, which, with confidential terms redacted, are filed as Exhibit 10.1 to this current report on Form 8-K.

Item 8.01 Other Information.

On September 30, 2020, the Company issued a press release announcing the settlement. A copy of the press release is filed as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1*	Settlement Agreement, dated September 29, 2020, by and among Collegium Pharmaceutical, Inc. and Teva Pharmaceuticals USA, Inc.
99.1	Press Release dated September 30, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Certain portions of the exhibits that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the Commission upon request.

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.

Dated: September 30, 2020

Collegium Pharmaceutical, Inc.

By: /s/ Paul Brannelly
Name: Paul Brannelly
Title: Executive Vice President and Chief Financial Officer

Exhibit 10.1

CERTAIN PORTIONS OF THE EXHIBIT THAT ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

SETTLEMENT AGREEMENT

This Settlement Agreement (including Exhibits A, B and C, the "Agreement") is made and entered into this 29th day of September, 2020 (the "Effective Date"), by and between, on the one hand, COLLEGIUM PHARMACEUTICAL, INC., a corporation organized under the laws of the Commonwealth of Virginia, having its principal place of business at 100 Technology Center Drive, Suite 300, Stoughton, MA 02072 ("Collegium"), and on the other hand, TEVA PHARMACEUTICALS USA, INC., a corporation organized under the laws of the state of Delaware, having its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054 ("Teva") (collectively Collegium and Teva may be referred to as the "Parties," or each separately, a "Party").

RECITALS

A. WHEREAS, Collegium owns and has the exclusive right to enforce U.S. Patent Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530; 9,763,883; 9,968,598; 10,004,729; and 10,188,644 (the "Patents-In-Suit"), which are listed in the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), in connection with Collegium's approved New Drug Application ("NDA") No. 208090 for XTAMPZA® ER (oxycodone) capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg;

B. WHEREAS, Teva has filed with FDA Abbreviated New Drug Application ("ANDA") No. 209431 for approval to market a generic version of XTAMPZA® ER (oxycodone) capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg (as amended, supplemented or replaced, "Teva ANDA");

C. WHEREAS, the Parties are parties to a lawsuit in the United States District Court for the District of Delaware (the "Court"), captioned *Collegium Pharmaceutical, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civ. A. No. 18-cv-0300-LPS-CJB (D. Del), *consolidated with* Civ. A. No. 18-cv-1900-LPS-CJB and Civ. A. No. 19-876-LPS-CJB (D. Del.), relating to the alleged infringement and validity of the Patents-In-Suit (the "Litigation");

D. WHEREAS, subject to the terms and conditions herein, Collegium has agreed to grant Teva a non-exclusive license to manufacture, use, offer for sale, and sell the generic products described in the Teva ANDA upon the terms and conditions set forth in this Settlement Agreement and in the License Agreement attached hereto as Exhibit B ("License Agreement");

E. WHEREAS, the Parties recognize the risks, unpredictability and expense of litigation and wish to resolve their dispute through a negotiated and consensual agreement;

F. WHEREAS, as a result of this Agreement, there may be an opportunity for pro-competitive U.S. competition for oxycodone products, which competition otherwise may not have existed until the expiration of the patents licensed under the License Agreement; and

G. WHEREAS, the Parties wish to settle the Litigation and all current and potential claims and counterclaims relating to the Teva ANDA and the generic products described therein, on the terms set forth herein in an effort to avoid further litigation and contain associated fees, costs, and expenses.

NOW THEREFORE, in consideration of the promises and mutual covenants set forth herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows.

1. Definitions. All capitalized terms used, but not otherwise defined in this Settlement Agreement, shall have the meanings set forth in the License Agreement.

2. License Agreement. Contemporaneously with the execution of this Settlement Agreement, Collegium and Teva shall enter into the License Agreement.

3. Costs and Expenses. Each Party shall bear its own fees and costs in connection with the preparation and execution of this Agreement.

4. Consent Judgment. In consideration of the mutual benefits of entering into this Agreement, the Parties will enter into and cause to be filed with the Court in the Litigation, within three (3) business days after the Effective Date, the Consent Judgment and Order of Permanent Injunction ("Consent Judgment") in the form attached hereto as Exhibit A. If for any reason the Court raises an objection to the Consent Judgment as drafted or requires that the Parties modify the Consent Judgment, the Parties agree to confer promptly and in good faith in order to take action consistent with the Agreement to secure entry of the Consent Judgment as drafted or with agreed-upon modifications, provided that nothing contained herein shall be deemed to require a Party to agree to a modification of the Agreement or Consent Judgment that materially affects the benefits to be obtained by, or burdens imposed upon, such Party under this Agreement as originally executed. If, after forty-five (45) days have elapsed from the date on which the Consent Judgment was filed, such efforts have failed to secure entry of the Consent Judgment as originally filed or with agreed-upon modifications, notwithstanding anything herein to the contrary, this Agreement shall be null and void and have no further legal effect.

5. Legal Compliance. The Parties shall submit the Agreement to the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice ("DOJ") as soon as practicable after the Effective Date, and in no event later than ten (10) business days after the Effective Date. To the extent that any legal or regulatory issues or barriers arise with respect to the Agreement, or any subpart thereof, the Parties shall use commercially reasonable efforts to: (i) respond promptly and in good faith to any requests for additional information made by either of such Agencies, (ii) coordinate any necessary or desirable joint presentation; and (iii) amend the Agreement to address any such objections in a way that is consistent with the Parties' intent. No Party shall be obliged to accept any modifications that frustrate the purpose of this Agreement or materially impair its value to such Party. Each Party reserves the right to communicate with the FTC or DOJ regarding such filings as it believes appropriate. Each Party shall keep the other Parties reasonably informed of such communications and, subject to the Confidentiality section below, shall not disclose any confidential information of the other Party without such other Party's consent, which shall not be unreasonably withheld or delayed.

6. **Released Claims.** In addition to entry of the Consent Judgment, Collegium and Teva make the following releases, which shall be effective upon entry of the Consent Judgment by the Court: (a) Teva for itself and its Affiliates hereby irrevocably releases and discharges Collegium and its Affiliates, successors, assigns, directors, officers, employees, agents, suppliers, distributors, and customers from all causes of action, demands, claims, damages, and liabilities of any nature, whether known or unknown, arising between Teva and/or its Affiliates and any of Collegium and/or its Affiliates from or in connection with the Litigation, the Teva ANDA, and/or the generic products described by the Teva ANDA and accruing or occurring prior to the Effective Date, including, without limitation, all claims, defenses, demands, and/or counterclaims that Teva and/or its Affiliates have asserted or could have asserted in the Litigation or in any other proceeding that any of the Licensed Patents is somehow invalid, unenforceable, not properly listed in the Orange Book, and/or not infringed by the filing of the Teva ANDA and/or the sale of the generic products described by the Teva ANDA in the Territory (all of the above collectively, "Teva Released Claims"); (b) Collegium for itself and its Affiliates hereby irrevocably releases and discharges Teva and its Affiliates, successors, assigns, directors, officers, employees, agents, suppliers, distributors, and customers from all causes of action, demands, claims, damages, and liabilities of any nature, whether known or unknown, arising between Collegium and/or its Affiliates and any of Teva and/or its Affiliates from or in connection with the Litigation, the Teva ANDA, and/or the generic products described by the Teva ANDA and accruing or occurring prior to the Effective Date, including, without limitation, all claims that Collegium and/or its Affiliates have asserted or could have asserted in the Litigation or in any other proceeding that any of the Licensed Patents is infringed by the Teva ANDA and/or the sale of the generic products described by the Teva ANDA in the Territory (all of the above collectively, the "Collegium Released Claims"); (c) this Agreement shall constitute a final settlement between the Parties in the Territory in connection with the Litigation and the Teva ANDA, and neither Teva nor its Affiliates shall institute any new challenge or litigation against Collegium and/or its Affiliates with respect to any of the Licensed Patents and the Teva ANDA, or actively assist or cooperate with any Third Party in any challenge or litigation against Collegium or its Affiliates with respect to the Licensed Patents unless so ordered by the Court or compelled by law; (d) Teva shall not allow any attorney, including outside counsel, to disclose or use any work product developed for or on behalf of Teva on or before the Effective Date; (e) no Party shall release any attorney who represented such Party in the Litigation from maintaining the confidentiality of non-public information to which such attorney had access in connection with the Litigation or grant any waivers with respect to such maintenance unless so ordered by the Court or compelled by law; and (f) to the extent necessary, Teva shall permit and cooperate with Collegium to enforce the obligations of such attorneys referred to under Sections 6(d) and 6(e). The Collegium Released Claims do not preclude Collegium from asserting infringement of any of the Licensed Patents in any action or proceeding against Teva and/or its Affiliates involving any product other than the Licensed Products. Notwithstanding anything to the contrary in this Section 6 or otherwise in this Agreement, nothing shall preclude a Teva API Affiliate or Teva Wholesaler Affiliate from contesting the infringement, validity and/or enforceability of the Licensed Patents – or assisting or cooperating with a Third Party to do the same -- in connection with a litigation or administrative proceeding concerning any product other than the Teva ANDA Products.

7. **No Challenge.** During the term of this Agreement, Teva, on behalf of itself and its Affiliates (but not including a Teva API Affiliate or Teva Wholesaler Affiliate with respect to a product other than the Teva ANDA Products), covenants and agrees that Teva and its Affiliates will not: (i) challenge, dispute or contest, directly or indirectly, the validity, enforceability, patentability, priority of invention or other claim to priority, or patent term adjustment of any of the Licensed Patents, or assert the non-infringement of the Licensed Patents, in each case, in any reexamination, *inter partes* proceeding, protest, observation, comment, third-party submission, opposition, post grant proceeding, *inter partes* review, post grant review, covered business method review, derivation proceeding, interference or other action or proceeding in the United States Patent and Trademark Office or in any court of law, or before any other government agency or tribunal, or submit or cause, in any manner, to be submitted, any filing, correspondence or communication in connection with any such action or proceeding; and (ii) assist, encourage, finance, or otherwise provide any information to, any Third Party in any such action or proceeding with respect to the Licensed Products or a Generic Equivalent under the foregoing clause. Notwithstanding the foregoing, nothing herein shall prevent Teva from maintaining a "Paragraph IV Certification" under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) within the Teva ANDA with respect to the Licensed Patents that may be listed in the Orange Book for the NDA Products.

8. **Admissions.** Teva acknowledges and agrees for itself and its Affiliates that, solely in connection with the Teva ANDA and Teva ANDA Products, (i) the Licensed Patents are valid and enforceable, and (ii) the Licensed Patents would be infringed by the manufacture, importation, use, offer for sale, or sale of the Teva ANDA Products in the Territory.

9. **ACKNOWLEDGMENTS.** Collegium and Teva acknowledge as follows:

(a) COLLEGIUM ACKNOWLEDGES THAT IT MAY HEREAFTER DISCOVER CLAIMS OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH IT NOW KNOWS OR BELIEVES TO EXIST WITH RESPECT TO THE COLLEGIUM RELEASED CLAIMS, THE FACTS AND CIRCUMSTANCES ALLEGED, AND/OR THE SUBJECT MATTER OF THIS AGREEMENT, WHICH, IF KNOWN OR SUSPECTED AT THE TIME OF EXECUTING THIS AGREEMENT, MAY HAVE MATERIALLY AFFECTED THIS AGREEMENT. NEVERTHELESS, UPON THE EFFECTIVENESS OF THE RELEASE OF THE COLLEGIUM RELEASED CLAIMS AS SET FORTH IN SECTION 6 ABOVE, COLLEGIUM HEREBY ACKNOWLEDGES THAT THE COLLEGIUM RELEASED CLAIMS INCLUDE WAIVERS OF ANY RIGHTS, CLAIMS OR CAUSES OF ACTION THAT MIGHT ARISE AS A RESULT OF SUCH DIFFERENT OR ADDITIONAL CLAIMS OR FACTS. COLLEGIUM ACKNOWLEDGES THAT IT UNDERSTANDS THE SIGNIFICANCE AND POTENTIAL CONSEQUENCES OF SUCH A RELEASE OF UNKNOWN UNITED STATES JURISDICTION CLAIMS AND OF SUCH A SPECIFIC WAIVER OF RIGHTS. COLLEGIUM INTENDS THAT THE CLAIMS RELEASED BY IT UNDER THIS RELEASE BE CONSTRUED AS BROADLY AS POSSIBLE TO THE EXTENT THEY RELATE TO UNITED STATES JURISDICTION CLAIMS. COLLEGIUM IS AWARE OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

> "A general release does not extend to claims that the creditor or released party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."

COLLEGIUM AGREES TO EXPRESSLY WAIVE ANY RIGHTS IT MAY HAVE UNDER THIS CODE SECTION OR UNDER FEDERAL, STATE OR COMMON LAW STATUTES OR JUDICIAL DECISIONS OF A SIMILAR NATURE, AND KNOWINGLY AND VOLUNTARILY WAIVES SUCH UNKNOWN CLAIMS.

(b) TEVA ACKNOWLEDGES THAT IT MAY HEREAFTER DISCOVER CLAIMS OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH IT NOW KNOWS OR BELIEVES TO EXIST WITH RESPECT TO THE TEVA RELEASED CLAIMS, THE FACTS AND CIRCUMSTANCES ALLEGED, AND/OR THE SUBJECT MATTER OF THIS AGREEMENT, WHICH, IF KNOWN OR SUSPECTED AT THE TIME OF EXECUTING THIS AGREEMENT, MAY HAVE MATERIALLY AFFECTED THIS AGREEMENT. NEVERTHELESS, UPON THE EFFECTIVENESS OF THE RELEASE OF THE TEVA RELEASED CLAIMS AS SET FORTH IN SECTION 6 ABOVE, TEVA HEREBY ACKNOWLEDGES THAT THE TEVA RELEASED CLAIMS INCLUDE WAIVERS OF ANY RIGHTS, CLAIMS OR CAUSES OF ACTION THAT MIGHT ARISE AS A RESULT OF SUCH DIFFERENT OR ADDITIONAL CLAIMS OR FACTS. TEVA ACKNOWLEDGES THAT IT UNDERSTANDS THE SIGNIFICANCE AND POTENTIAL CONSEQUENCES OF SUCH A RELEASE OF UNKNOWN UNITED STATES JURISDICTION CLAIMS AND OF SUCH A SPECIFIC WAIVER OF RIGHTS. TEVA INTENDS THAT THE CLAIMS RELEASED BY IT UNDER THIS RELEASE BE CONSTRUED AS BROADLY AS POSSIBLE TO THE EXTENT THEY RELATE TO UNITED STATES JURISDICTION CLAIMS. TEVA IS AWARE OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

> "A general release does not extend to claims that the creditor or released party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."

TEVA AGREES TO EXPRESSLY WAIVE ANY RIGHTS IT MAY HAVE UNDER THIS CODE SECTION OR UNDER FEDERAL, STATE OR COMMON LAW STATUTES OR JUDICIAL DECISIONS OF A SIMILAR NATURE, AND KNOWINGLY AND VOLUNTARILY WAIVES SUCH UNKNOWN CLAIMS.

10. **Confidentiality.** The terms of the Agreement shall be maintained in strict confidence by the Parties except: (a) as provided by Section 5 of this Settlement Agreement; (b) that any Party may disclose such terms if and as required by law, including, without limitation, SEC reporting requirements, or by the rules or regulations of any stock exchange that the Parties are subject to; (c) Collegium may disclose such terms as may be necessary in connection with any settlement discussions relating to the Licensed Patents, NDA Products, or Xtampza® ER NDA, (d) Collegium may issue a press release in the form attached hereto at Exhibit C, or (e) as otherwise agreed to by the Parties. If a Party is disclosing information relating to the Agreement because it is required to do so to comply with statutory, regulatory or legal process requirements, including its reporting requirements under the SEC rules, or any national securities exchange on which it is listed, such Party intending to make such disclosure shall give the other Party at least two (2) business days prior notice in writing of the text of the intended disclosure, unless such statutory, regulatory or legal process requirements would require earlier disclosure, in which event, the notice shall be provided as early as practicable. A disclosing Party agrees to request confidential treatment with respect to the terms of the Agreement and to use commercially reasonable efforts to have redacted such provisions of the Agreement as the Parties may agree from any copies filed pursuant to such statutory, regulatory or legal process requirements. If either Party determines that it will be required to file the Agreement as provided above, promptly after the giving of notice by such Party as contemplated above, the Parties will use commercially reasonable efforts to agree on those provisions of the Agreement that the Parties will seek to have redacted as provided above. If the Parties are unable to agree on the provisions of the Agreement that the Parties will seek to have redacted, the disclosure shall be limited to the minimum required, as determined by the Party required to make such disclosure in consultation with its legal counsel. Each Party may disclose the terms of the Agreement to its respective Affiliates, and each of its and their insurers, lenders, attorneys, auditors, accountants, licensors, licensees, prospective licensees, prospective assignees, and potential investors, acquirors or transferees, subject to such Affiliates, insurers, lenders, attorneys, auditors, accountants, licensors, licensees, prospective licensees, prospective assignees, and potential investors, acquirors or transferees, being bound by confidentiality obligations at least as stringent as those set forth in this Section 10.

11. **Term and Termination.** This Settlement Agreement shall continue from the Effective Date until the earlier of: (a) the expiration of the last to expire of the Licensed Patents; or (b) the date of a final decision by a United States court or administrative agency, from which no appeal has been or can be taken, that all claims of the Licensed Patents are invalid or unenforceable. The releases and discharges set forth in Section 6 of this Settlement Agreement shall survive the expiration, but not termination, of the Agreement and the confidentiality obligations set forth in Section 10, above, shall survive for a period of twenty (20) years from the Effective Date, notwithstanding any earlier expiration or termination of the Agreement. In addition, this Section 11 and Sections 7, 8, 14, 15 and 16 shall survive the expiration or termination of the Settlement Agreement, the License Agreement, or the Agreement as a whole. The License Agreement shall remain in full force and effect pursuant to its own terms notwithstanding the expiration or termination of this Settlement Agreement. Notwithstanding the foregoing, if Teva or its Affiliates, directly or indirectly, breaches any of its obligations and restrictions under Section 7 of this Settlement Agreement, then Collegium may terminate this Settlement Agreement or the Agreement as a whole, including all licenses and covenants granted by Collegium under the License Agreement, without prior notice or an opportunity to cure, and Teva hereby stipulates to the entry of a preliminary injunction (without bond or other security) and permanent injunction (without a showing of irreparable harm or that legal remedies are inadequate) to prevent such a breach or the continuance of such breach.

12. **No Assignment.** The Agreement may not be assigned or transferred to a Third Party without the express prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or otherwise conditioned. Notwithstanding the above, Collegium may, without such consent, assign or transfer the Agreement (a) to an Affiliate, or (b) to a successor to all or substantially all of the business of Collegium to which the Agreement pertains (*i.e.*, the Licensed Patents or the NDA Product), whether by sale of stock, merger, transfer, consolidation or otherwise, in which case Collegium shall assign the Agreement, in full, to such successor. Further, notwithstanding the above, Teva may, without such consent, assign or transfer the Agreement (a) to an Affiliate, or (b) to a successor to all or substantially all of Teva's generics business, whether by sale of stock, merger, transfer, consolidation or otherwise, in which case Teva shall assign the Agreement, in full, to such successor. Any attempted assignment or transfer in violation of the provisions of this Section shall be null and void. The covenants, rights and obligations of a Party under this Agreement shall remain binding upon the transferring Party and shall inure to the benefit of and be binding upon any successor or permitted assignee of the Party. For the avoidance of doubt, any assignment of this Agreement must be made in full, inclusive of both the Settlement Agreement and License Agreement, and any attempted assignment of the Settlement Agreement, alone, or the License Agreement, alone, shall be null and void.

13. Representations and Warranties. Each Party represents and warrants to the other Party as follows:

(a) the Party has obtained the advice of legal counsel prior to such Party's execution and delivery of the Agreement, and that such Party's execution and delivery of the Agreement, including the releases set forth above, are made voluntarily, with full knowledge of their significance, and with the express intention of performing all obligations;

(b) the Agreement has been duly executed and delivered and constitutes the legal, valid, and binding obligations of such Party, enforceable in accordance with their terms;

(c) the execution, delivery and performance of the Agreement does not and will not violate or conflict with any provision of such Party's organizational documents or bylaws as in effect on the date hereof;

(d) it has the power and authority to enter into the Agreement and has taken all necessary corporate action to authorize its performance under the Agreement;

(e) no consent or authorization of any governmental authority is required in connection with its performance under the Agreement;

(f) to its knowledge, its entering into the Agreement or performance by it under the Agreement will not violate any federal, state or local licensing or other statute, rule or regulation, or any contractual obligation of such Party;

(g) the Party: (i) has read the Agreement, (ii) fully understands all the terms and conditions thereof and the meaning of each provision thereof (including specifically the releases and covenants contained herein) and (iii) has entered into the Agreement of its own free will and volition, and that it has been advised to consult counsel, that it has had the opportunity to consult with an attorney concerning the Agreement and that it freely and voluntarily enters into the Agreement;

(h) the Agreement was negotiated by the Parties on an arms' length basis; and

(i) Each Party represents and warrants to the other Parties that the rights and obligations exchanged pursuant to the Agreement constitute the sole consideration being exchanged between or among any of the Parties in connection with the Agreement and no other form of compensation or other accommodation has been made between or among any of the Parties.

14. **Notice.** Any notice required or permitted to be given or sent under this Agreement shall be hand delivered or sent by express delivery service or certified or registered mail, postage prepaid, to the Parties at the addresses indicated below.

If to Collegium, to:
Collegium Pharmaceutical, Inc.
100 Technology Center Drive
Suite 300
Stoughton, MA 02072
Attention: Senior Counsel, Head of Intellectual Property

with copies (which shall not constitute notice hereunder) to:

Robins Kaplan LLP
800 LaSalle Avenue
Suite 2800
Minneapolis, MN 55402
Attention: Jake M. Holdreith

Rakoczy Molino Mazzochi Siwik LLP
6 W. Hubbard Street
Suite 500
Chicago, Illinois 60654
Attention: William A. Rakoczy

If to Teva, to:

Teva Pharmaceuticals USA, Inc.
400 Interpace Parkway, #3
Parsippany, NJ 07054
Attention: Chief IP Counsel

with copies (which shall not constitute notice hereunder) to:

Greenberg Traurig, LLP
MetLife Building
200 Park Avenue
New York, NY 10166
Attention: Scott Bornstein

Any such notice shall be deemed to have been received on the date actually received. Either Party may change its address by giving the other Party written notice, delivered in accordance with this Section.

15. **Entire Agreement.** This Agreement, once duly executed by all Parties, constitutes the complete, final and exclusive agreement between the Parties with respect to the subject matter hereof and supersedes and terminates any prior or contemporaneous agreements and/or understandings between the Parties, whether oral or in writing. There are no other covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in the Agreement. No subsequent alteration, amendment, change, waiver or addition to the Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. Each Party in deciding to execute the Agreement has retained counsel and has not relied on any understanding, agreement, representation or promise by the other Party that is not explicitly set forth herein.

16. **Governing Law.** The Agreement shall be governed, interpreted and construed in accordance with the laws of the State of Delaware, without giving effect to choice of law principles. The Parties irrevocably agree that the federal district court in the State of Delaware shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with the Agreement and that, accordingly, any proceedings arising out of or in connection with the Agreement shall be brought in the United States District Court for the District of Delaware. Notwithstanding the foregoing, if there is any dispute for which the federal district court in the State of Delaware does not have subject matter jurisdiction, the state courts in Delaware shall have jurisdiction. In connection with any dispute arising out of or in connection with the Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the State of Delaware.

17. **Severability.** Subject to Section 5 above, if any provision of the Agreement is declared illegal, invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that the Agreement shall endure except for the part declared invalid or unenforceable by order of such court; provided, however, that in the event that the terms and conditions of the Agreement are materially altered, the Parties will, in good faith, renegotiate the terms and conditions of the Agreement to reasonably replace such invalid or unenforceable provisions in light of the intent of the Agreement.

18. **Amendments.** No amendment, modification or supplement of any provisions of the Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

19. **Waiver.** Any delay or failure in enforcing a Party's rights under the Agreement, or any acquiescence as to a particular default or other matter, shall not constitute a waiver of such Party's rights to the enforcement of such rights, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, except as to an express written and signed waiver as to a particular matter for a particular period of time.

20. **Construction.** The Agreement has been jointly negotiated and drafted by the Parties through their respective counsel and no provision shall be construed or interpreted for or against any of the Parties on the basis that such provision, or any other provision, or the Agreement as a whole, was purportedly drafted by the particular Party. As used in the Agreement, neutral pronouns and any variations thereof shall be deemed to include the feminine and masculine and all terms used in the singular shall be deemed to include the plural, and vice versa, as the context may require. The words "herein," "hereof" and "hereunder" and other words of similar import refer to the Agreement as a whole, as the same may from time to time be amended or supplemented, and not to any particular subdivision contained in the Agreement. The word "including" when used herein is not intended to be exclusive, or to limit the generality of the preceding words, and means "including, without limitation." Where a Party's consent is required hereunder, except as otherwise specified herein, such Party's consent may be granted or withheld in such Party's sole discretion.

21. **Counterparts**. This Settlement Agreement shall become binding when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the Parties hereto. The Settlement Agreement may be executed simultaneously in any number of counterparts (including facsimile or e-mail counterparts), each of which will be deemed an original as against a Party whose signature appears thereon, but all of which together will constitute one and the same instrument.

22. **Captions**. The captions of this Settlement Agreement are solely for convenience of reference and will not affect its interpretation.

23. **Negation of Agency**. Nothing contained herein will be deemed to create any relationship, whether in the nature of agency, joint venture, partnership or otherwise, between Collegium and Teva. No Party will be authorized to bind or obligate the other Party in any manner.

[*Signature page follows*]

IN WITNESS WHEREOF, this Settlement Agreement has been executed by the duly authorized representatives of the Parties as of the date and year first above written.

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Shirley Kuhlmann
Name: Shirley Kuhlmann
Title: EVP and General Counsel

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Christine Baeder
Name: Christine Baeder
Title: SVP Customer Operations

By: /s/ Colman Ragan
Name: Colman Ragan
Title: VP and GC North America IP Litigation

EXHIBIT A

Consent Judgment

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COLLEGIUM PHARMACEUTICAL, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 18-300-LPS-CJB C.A. No. 18-1900-LPS-CJB CONSOLIDATED C.A. No. 19-876-LPS-CJB

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement having been brought by Plaintiff Collegium Pharmaceutical, Inc. ("Collegium") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") for infringement of United States Patent Nos. 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530; 9,763,883; 9,968,598; 10,004,729; 10,188,644 (the "Asserted Patents");

In response to Collegium's assertions of patent infringement, Teva has alleged certain defenses, claims and counterclaims relating to the Asserted Patents and United States Patent No. 7,399,488 (collectively with the Asserted Patents, the "Litigated Patents");

Collegium and Teva have entered into a Settlement Agreement and License Agreement (collectively, the "Agreement"), under which Collegium will grant Teva a license to the Litigated Patents (the "License"), pursuant to the terms and conditions in the Agreement and License;

Teva acknowledges that, solely in connection with the Teva ANDA and Teva ANDA Product, the Litigated Patents, and all claims contained therein, are valid and enforceable; and

Teva acknowledges that using, making, offering for sale, selling, and/or importing in or into the United States any oxycodone extended-release capsule product under Abbreviated New Drug Application No. 209431 ("Teva's ANDA Product") would infringe each of the Litigated Patents in the absence of a license.

Collegium and Teva now consent to this Judgment and Order.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED:

1. This Court has jurisdiction over the parties and the subject matter of this action.

2. Teva would infringe each of the Litigated Patents by using, making, offering to sell, selling, and/or importing Teva's ANDA Product in or into the United States.

3. The Litigated Patents, and all claims contained therein, are valid and enforceable, solely with respect to the Teva ANDA and Teva ANDA Product.

4. All affirmative defenses, claims, and counterclaims which have been or could have been raised by Teva in this action with respect to the Litigated Patents are dismissed with prejudice.

5. Except as authorized and licensed by Collegium under the License, Teva, its officers, agents, employees, affiliates, successors and all persons in active concert or participation with Teva, are permanently enjoined from using, making, offering for sale, or selling in the United States, or importing into the United States, Teva's ANDA Product and/or inducing or assisting others to use, make, offer for sale, or sell in the United States, or import into the United States, Teva's ANDA Product.

6. In any other or future cause of action or litigation in the United States, Teva shall not dispute that any of the Litigated Patents are infringed by using, making, offering to sell, or selling in the United States, or importing into the United States, Teva's ANDA Product.

7. In any other or future cause of action or litigation in the United States involving Teva's ANDA Product, Teva shall not dispute that all claims of the Litigated Patents are valid and enforceable in all respects.

8. The foregoing injunctions against Teva shall take effect immediately upon entry of this Judgment and Order by the Court, and shall continue until the expiration of the Litigated Patents.

9. Nothing herein prohibits or is intended to prohibit Teva from maintaining and/or (e.g. in the case of a recertification pursuant to 21 C.F.R. § 314.96(d)) filing a "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to any of the Litigated Patents, and/or filing a "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to any other patents which may be listed in the Orange Book for Xtampza ER.

10. Nothing herein prohibits or is intended to prohibit the FDA from granting final approval of the Teva ANDA at any time.

11. This Judgment and Order is binding upon and constitutes claim preclusion and issue preclusion between the parties in this action or in any other action in the United States between the parties with respect to: (i) the validity and enforceability of the Litigated Patents, solely in connection with the Teva ANDA and Teva ANDA Product, and (ii) infringement of the Litigated Patents by using, making, selling, offering to sell, and/or importing Teva's ANDA Product.

12. The parties waive all right to appeal from this Judgment and Order.

13. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcing the provisions of this Judgment and Order and the terms of the parties' Agreement and License, and any disputes that may arise thereunder.

14. Each party is to bear its own costs and attorneys' fees.

Dated: _____ __, 2020

s/

Frederick L. Cottrell, III (No. 2555)
Kelly E. Farnan (No. 4395)
Christine D. Haynes (No. 4697)
RICHARDS, LAYTON & FINGER, P.A.
920 N. King Street
Wilmington, DE 19081
(302) 651-7700
cottrell@rlf.com
farnan@rlf.com
haynes@rlf.com

Attorneys for Plaintiff

s/

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

Attorneys for Defendant

SO ORDERED this __ day of _____, 2020 _____

United States District Judge

EXHIBIT B

License Agreement

CERTAIN PORTIONS OF THE EXHIBIT THAT ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

LICENSE AGREEMENT

This License Agreement (the "License Agreement") is made and entered into this 29th day of September, 2020 (the "Execution Date"), by and between, on the one hand, COLLEGIUM PHARMACEUTICAL, INC., a corporation organized under the laws of the Commonwealth of Virginia, having its principal place of business at 100 Technology Center Drive, Suite 300, Stoughton, MA 02072 ("Collegium"), and on the other hand, TEVA PHARMACEUTICALS USA, INC., a corporation organized under the laws of the state of Delaware, having its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054 ("Teva") (collectively, Collegium and Teva may be referred to as the "Parties," or each separately, a "Party").

RECITALS

A. Collegium owns and has the exclusive right to enforce U.S. Patent Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530; 9,763,883; 9,968,598; 10,004,729; 10,188,644 (the "Patents-In-Suit"), which are listed in the Orange Book (as hereinafter defined), in connection with Collegium's approved New Drug Application No. 208090 for XTAMPZA® ER (oxycodone) capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg;

B. Teva has filed with the FDA (as hereinafter defined) Abbreviated New Drug Application No. 209431 for approval to market a generic version of XTAMPZA® ER (oxycodone) capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg;

C. The Parties are parties to a lawsuit in the United States District Court for the District of Delaware, captioned *Collegium Pharmaceutical, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civ. A. No. 18-cv-0300-LPS-CJB (D. Del), *consolidated with* Civ. A. No. 18-cv-1900-LPS-CJB and Civ. A. No. 19-876-LPS-CJB (D. Del.), relating to the alleged infringement and validity of the Patents-In-Suit;

D. Pursuant to a Settlement Agreement to which this License Agreement is Exhibit B (the "Settlement Agreement"), executed contemporaneously with this License Agreement, Collegium and Teva have agreed to settle existing and potential claims and disputes related to the Licensed Products (as hereinafter defined); and

E. As part of such settlement, Collegium and Teva agreed to enter into this License Agreement, which, upon the terms set forth herein, grants Teva, *inter alia*, a non-exclusive license under the Licensed Patents to Manufacture and/or Market, as applicable, in or for the Territory the Licensed Products (as such capitalized terms are hereinafter defined).

NOW THEREFORE, in consideration of the promises and mutual covenants set forth herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows.

1. Definitions. As used herein, the following capitalized terms shall have the meanings ascribed to them below.

1.1 "Affiliate" shall mean any person or entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Party. For the purposes of this definition, "control" (including the terms "controlled by" and "under common control with") means (i) the direct or indirect ownership of fifty percent (50%) or more of the voting stock or other voting interest in such entity, (ii) the right to appoint fifty percent (50%) or more of the directors or management of such entity, or (iii) the power to otherwise control or direct the decisions of the board of directors or similar body governing the affairs of such entity.

1.2 "ANDA" shall mean an abbreviated new drug application under 21 U.S.C. § 355(j) (or equivalent regulatory mechanism).

1.3 "API" shall mean active pharmaceutical ingredient(s).

1.4 "FDA" shall mean the U.S. Food and Drug Administration (and any successor organization or agency thereto).

1.5 "Final Court Decision" shall mean a decision of a United States court or administrative agency from which no appeal has been or can be taken, excluding any petition for a writ of certiorari or other proceedings before the Unites States Supreme Court. For the avoidance of doubt, a decision of an appeals court is final upon entry of the mandate.

1.6 "Generic Equivalent" shall mean a pharmaceutical product that is Marketed or intended for Marketing in the Territory pursuant to an approved ANDA as an A-rated generic equivalent to any of the NDA Products.

1.7 "Licensed Launch Date" shall mean the earlier of:

(a) September 2, 2033;

(b) [***];

(c) [***];

(d) [***].

1.8 "Licensed Patents" shall mean, collectively, the Patents-In-Suit, and any other patents listed in the Orange Book in connection with the Xtampza® ER NDA, along with any corrections, extensions, continuations, continuations-in-part, divisionals, reissues, or reexaminations of the same.

1.9 "Licensed Products" shall mean the Teva ANDA Products, as defined below.

1.10 "Manufacture" shall mean to manufacture, and/or have manufactured, a pharmaceutical product.

1.11 **"Market"** shall mean to market, sell, have sold, offer to sell and have offered for sale, distribute and have distributed, a pharmaceutical product and/or to import such product for such purposes, and "Marketing" shall have a corresponding meaning.

1.12 **"NDA"** shall mean a new drug application under 21 U.S.C. § 355(b)(1) or 21 U.S.C. § 355(b)(2) (or equivalent regulatory mechanism).

1.13 **"NDA Products"** shall mean the products that are the subject of the Xtampza® ER NDA.

1.14 **"Orange Book"** shall mean "*Approved Drug Products with Therapeutic Equivalence Evaluations*" published by FDA in connection with approved drug products, or any successor publication thereto.

1.15 **"Paragraph IV Certification"** shall mean a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced).

1.16 "**Person**" shall mean an individual, partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, governmental authority, or other entity of whatever nature.

1.17 **"Proceeding"** shall mean any action, audit, litigation, investigation, suit, or other proceeding.

1.18 **"Territory"** shall mean the United States of America, including its territories, possessions and commonwealths.

1.19 **"Teva ANDA"** shall mean Teva's ANDA No. 209431 for oxycodone extended-release capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg, including any amendments, supplements or replacements thereto.

1.20 **"Teva ANDA Products"** shall mean the oxycodone extended-release capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg, that are the subject of the Teva ANDA.

1.21 **"Teva API Affiliate"** shall mean an Affiliate of Teva whose sole business is in the manufacture of API. For the avoidance of doubt, a Teva API Affiliate shall not include any Affiliate of Teva that files, owns or maintains NDAs, ANDAs or applications submitted under 21 U.S.C. § 355(b)(2).

1.22 **"Teva Wholesaler Affiliate"** shall mean an Affiliate of Teva whose sole business is in the wholesale distribution of pharmaceutical products. For the avoidance of doubt, a Teva Wholesaler Affiliate shall not include any Affiliate of Teva that files, owns or maintains NDAs, ANDAs or applications submitted under 21 U.S.C. § 355(b)(2). For the further avoidance of doubt, [***].

1.23 **"Third Party"** shall mean any Person or entity other than a Party or its Affiliates.

1.24 **"Trademark"** shall mean the trademark XTAMPZA® and any replacement trademark.

1.25 **"Xtampza® ER NDA"** shall mean NDA No. 208090 for XTAMPZA® ER (oxycodone) capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg, including any amendment or supplement thereto.

2. License and Covenants.

2.1 **License.** Collegium, for itself and its Affiliates, hereby grants Teva and its Affiliates, on and after the Licensed Launch Date, a non-exclusive, non-sublicensable, non-transferable license under the Licensed Patents to Manufacture, use, have used, and Market in or for the Territory the Licensed Products. For the avoidance of doubt, the right and license granted under this Section 2.1 shall not apply to the Manufacture or distribution of Teva ANDA Products for sale to Third Parties for use or consumption outside the Territory. For the further avoidance of doubt, the right and license granted under this Section 2.1 shall not apply to the Manufacture or distribution of any finished product aside from the Teva ANDA Products, or to the supply of API or any other ingredients for any finished product aside from the Teva ANDA Products.

2.2 **Pre-Booking Activities.** Notwithstanding anything to the contrary contained in Section 2.1, prior to the Licensed Launch Date, Teva may engage in the following pre-booking activities:

(a) Manufacture of the Licensed Products inside the Territory, and/or importation of the Licensed Products into the Territory, starting not earlier than [***] prior to the Licensed Launch Date;

(b) Discussions with potential customers to make them aware of the upcoming availability of the Licensed Products from Teva, starting not earlier than [***] prior to the Licensed Launch Date;

(c) Non-binding offers for sale starting not earlier than [***] prior to the Licensed Launch Date.

2.3 **Limitations on License.** Except to the extent permitted by the License of Section 2.1, and the permitted pre-booking activities of Section 2.2, neither Teva nor any of its Affiliates, distributors or agents shall under any circumstances Manufacture or Market any Generic Equivalent in or for the Territory prior to the expiration of the last to expire of the Licensed Patents.

2.4 **Collegium Covenant-Not-To-Sue.** As of the Execution Date, Collegium hereby finally and irrevocably covenants, for itself and its Affiliates, that it will not sue, assert any claim or counterclaim against, or otherwise participate in any action or proceeding against Teva or any of its Affiliates, shareholders, customers, suppliers, importers, manufacturers, agents or other personnel, insurers, or any heirs, administrators, executors, predecessors, or permitted successors and assigns of the foregoing, or cause or authorize any Person or entity to do any of the foregoing, in each case claiming or otherwise asserting that the Manufacture, use, and Marketing of the Licensed Products as of the Licensed Launch Date (or as otherwise permitted pursuant to Section 2.2, above), in or for the Territory, infringes the Licensed Patents or any other United States patents owned or otherwise controlled by Collegium or any of its Affiliates that cover the NDA Products and/or the Teva ANDA Products. For clarity, as used herein, "controlled" means the ability to grant a license or sublicense to a patent without violating the terms of, or incurring any royalty or other financial obligation under, any written agreement with an unaffiliated Third Party. Collegium will impose the foregoing Covenant-Not-To-Sue on any Third Party to which Collegium may assign, exclusively license or otherwise transfer any of the Licensed Patents or any other relevant patent.

2.5 **Teva Covenant-Not-To-Sue.** As of the Execution Date, Teva hereby finally and irrevocably covenants, for itself and its Affiliates, that it will not sue, assert any claim or counterclaim against, or otherwise participate in any action or proceeding against Collegium or any of its Affiliates, shareholders, customers, suppliers, importers, manufacturers, agents or other personnel, insurers, or any heirs, administrators, executors, predecessors, or permitted successors and assigns of the foregoing, or cause or authorize any Person or entity to do any of the foregoing, in each case claiming or otherwise asserting that the Manufacture, use, and Marketing of the NDA Products, in or for the Territory, infringes any patents owned, licensed or otherwise controlled by Teva or its Affiliates. Teva will impose the foregoing Covenant-Not-To-Sue on any Third Party to which Teva may assign, exclusively license or otherwise transfer any such relevant patent.

2.6 **[***]**

3. **Notice and Acknowledgements.**

3.1 Except to the extent expressly permitted by Section 2.1 or Section 2.2 of this License Agreement, unless this License Agreement is earlier terminated in accordance with the terms hereof, neither Teva nor any of its Affiliates shall under any circumstances Manufacture or Market any Generic Equivalent in the Territory prior to the expiration of the Licensed Patents.

3.2 Teva acknowledges that Manufacturing or Marketing the Teva ANDA Products outside the scope of the License and other rights granted in this License Agreement would cause Collegium irreparable harm. Teva further acknowledges that Collegium shall be entitled to specific enforcement of the terms and conditions set forth in this License Agreement and shall be entitled to immediate injunctive relief (without bond or security, or any showing of irreparable harm) to prevent Teva and/or its Affiliates from Manufacturing or Marketing the Teva ANDA Products outside the scope of this License Agreement.

4. **Reservation of Rights.**

4.1 Notwithstanding anything to the contrary herein, Collegium and its Affiliates grant no rights to Teva and its Affiliates under the Xtampza® ER NDA.

4.2 All rights not expressly granted to Teva hereunder are expressly reserved to Collegium, and Collegium has no obligation to make available any intellectual property rights or to take any other actions other than as expressly set forth herein. Nothing in this License Agreement shall be construed as granting Teva or its Affiliates (i) any rights with respect to any products outside the Territory; (ii) any rights with respect to any product other than the Teva ANDA Products; or (iii) except as expressly provided herein, any license, sublicense or other right to any patents, any other intellectual property or any regulatory exclusivities or approvals held by Collegium or any of its Affiliates. For the sake of clarity, this License Agreement does not grant to Teva or its Affiliates any right to use any corporate names, logos or trademarks (including any Trademark) of Collegium or any of its Affiliates inside or outside the Territory.

5. Representations and Warranties.

5.1 Each Party represents and warrants to the other Party that the execution and delivery by such Party of this License Agreement and the performance of its obligations hereunder have been duly authorized by all necessary corporate action and do not conflict with the terms of any other contract, agreement, arrangement, or understanding to which such Party is a party.

5.2 Collegium represents and warrants that it has the right to license the Licensed Patents to Teva under the terms and conditions set forth in the Agreement. To the extent Collegium or any of its Affiliates assigns, licenses, sublicenses, or otherwise transfers (by any means) to any Third Party any right, title or interest in or to the Licensed Patents that could be asserted against the Teva ANDA Products after the Effective Date, Collegium, or such Affiliates, will make such assignment, license, sublicense or other transfer subject to the license, covenants and other rights granted to Teva under Section 2.

5.3 Teva represents, warrants, and covenants that, as of the Execution Date: (i) Teva is the true and sole owner of ANDA No. 209431, and Teva and its Affiliates have not assigned or otherwise transferred ownership to any Third Party; (ii) Teva is the sole "first applicant," as described in 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (as amended or replaced), for a generic version of the NDA Products; (iii) Teva and its Affiliates will undertake commercially reasonable efforts, as of and after the Execution Date, to maintain Teva's status as the "first applicant"; and (iv) Teva and its Affiliates will not (until the expiration of the last to expire of the Licensed Patents) assist, authorize or cooperate with any Third Party in Manufacturing, using, Marketing, or seeking regulatory approval for an unlicensed ANDA or NDA product referencing the Xtampza® ER NDA**.**

6. Term and Termination.

6.1 **Expiration.** Unless earlier terminated in accordance with the terms hereof, the term of this License Agreement (the "Term") shall extend from the Execution Date until the earlier of: (a) the expiration of the last to expire of the Licensed Patents; or (b) the date of a Final Court Decision holding that all claims of the Licensed Patents are invalid or unenforceable.

6.2 **Breach.** Each Party may terminate this License Agreement and its obligations hereunder in the event of a material breach by the other Party that remains uncured for five (5) business days after the other Party specifies in reasonable detail in writing the nature of the breach and demands its cure.

(a) Notwithstanding the foregoing, the Parties acknowledge and agree that the Manufacture and/or Marketing by Teva or any of its Affiliates of any Teva ANDA Products or (except in the case of a Teva API Affiliate or Teva Wholesaler Affiliate with respect to a product other than the Teva ANDA Products) any Generic Equivalent in the Territory prior to the Licensed Launch Date, or as otherwise permitted under Section 2.2, shall constitute an immediate material breach by Teva of this License Agreement for which Collegium may elect to terminate this License Agreement without prior notice or an opportunity to cure.

6.3 **Accrued Obligations; Survival.** Expiration or termination of this License Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or early termination of this License Agreement shall be without prejudice to the rights of any Party against any other Party accrued or accruing under this License Agreement prior to such expiration or termination. The provisions of Sections 1, 3, 4, 5, 6, 7, and 8 of this License Agreement shall survive any expiration or termination of this License Agreement.

7. **Notice.** Any notice required or permitted to be given or sent under this License Agreement shall be hand delivered or sent by express delivery service or certified or registered mail, postage prepaid, to the Parties at the addresses indicated below.

If to Collegium, to:

Collegium Pharmaceutical, Inc.
100 Technology Center Drive
Suite 300
Stoughton, MA 02072
Attention: Senior Counsel, Head of Intellectual Property

with copies (which shall not constitute notice hereunder) to:

Robins Kaplan LLP
800 LaSalle Avenue
Suite 2800
Minneapolis, MN 55402
Attention: Jake M. Holdreith

Rakoczy Molino Mazzochi Siwik LLP
6 W. Hubbard Street
Suite 500
Chicago, Illinois 60654
Attention: William A. Rakoczy

If to Teva, to:

Teva Pharmaceuticals USA, Inc.
400 Interpace Parkway
Parsippany, NJ 07054
Attention: Chief IP Counsel

with copies (which shall not constitute notice hereunder) to:

Greenberg Traurig, LLP
MetLife Building
200 Park Avenue
New York, NY 10166
Attention: Scott Bornstein

Any such notice shall be deemed to have been received on the date actually received. Either Party may change its address by giving the other Party written notice, delivered in accordance with this Section.

8. **Governing Law.** This License Agreement shall be governed, interpreted and construed in accordance with the laws of the State of Delaware, without giving effect to choice of law principles. The Parties irrevocably agree that the federal district court in the State of Delaware shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this License Agreement and that, accordingly, any proceedings arising out of or in connection with this License Agreement shall be brought in the United States District Court for the District of Delaware. Notwithstanding the foregoing, if there is any dispute for which the federal district court in the State of Delaware does not have subject matter jurisdiction, the state courts in Delaware shall have jurisdiction. In connection with any dispute arising out of or in connection with this License Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the State of Delaware.

9. **Amendments.** No amendment, modification or supplement of any provisions of this License Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

10. **Counterparts**. This License Agreement shall become binding when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the Parties hereto. The License Agreement may be executed simultaneously in any number of counterparts (including facsimile or e-mail counterparts), each of which will be deemed an original as against a Party whose signature appears thereon, but all of which together will constitute one and the same instrument.

11. **Captions**. The captions of this License Agreement are solely for convenience of reference and will not affect its interpretation.

12. **Negation of Agency**. Nothing contained herein will be deemed to create any relationship, whether in the nature of agency, joint venture, partnership or otherwise, between Collegium and Teva. No Party will be authorized to bind or obligate the other Party in any manner.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the undersigned have executed this License Agreement as of the date and year first above written.

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Shirley Kuhlmann
Name: Shirley Kuhlmann
Title: EVP and General Counsel

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Christine Baeder
Name: Christine Baeder
Title: SVP Customer Operations

By: /s/ Colman Ragan
Name: Colman Ragan
Title: VP and GC North America IP Litigation

EXHIBIT C

Collegium Press Release

Exhibit 99.1

Collegium Announces Settlement with Teva Resolving Xtampza® ER Patent Litigation

STOUGHTON, Mass., September 30, 2020 -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a specialty pharmaceutical company committed to being the leader in responsible pain management, today announced that it has reached a settlement agreement with Teva Pharmaceuticals USA, Inc. (Teva) that resolves patent litigation brought in response to Teva's Abbreviated New Drug Application (ANDA), seeking approval to market a generic version of Xtampza ER prior to the expiration of Collegium's applicable patents.

Pursuant to the terms of the settlement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, Collegium will grant Teva a license to market its generic version of Xtampza ER in the United States beginning on or after September 2, 2033 (subject to U.S. FDA approval, and acceleration under certain circumstances). As a result of the settlement, Teva has agreed to a consent judgment confirming that its proposed generic products infringe Collegium's asserted patents and that those patents are valid and enforceable with respect to Teva's proposed generic products. Additional details regarding the settlement are confidential.

"As a company committed to being the leader in responsible pain management, we seek to deliver scientific innovation through differentiated products for people suffering from pain. We are pleased with the outcome of the ANDA settlement with Teva because it highlights the value of that innovation in the context of the Xtampza ER franchise," said Shirley Kuhlmann, Executive Vice President and General Counsel of Collegium. "The resolution of this litigation reinforces the strength of Collegium's intellectual property portfolio, which includes 19 Orange Book-listed patents covering Xtampza ER with expiries through 2036, and our commitment to innovation in responsible pain management."

About Collegium Pharmaceutical, Inc.

Collegium is a specialty pharmaceutical company committed to being the leader in responsible pain management. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit the company's website at www.collegiumpharma.com.

Contact:
Alex Dasalla
adasalla@collegiumpharma.com