# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **June 13, 2024**

# 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 8.01 Other Information.**

On June 13, 2024, Collegium Pharmaceutical, Inc. issued a press release announcing the U.S. Food and Drug Administration ("FDA") has granted pediatric exclusivity for Nucynta® and Nucynta® ER ("the Nucynta Franchise"), extending exclusivity of the Nucynta Franchise an additional six months, to January 3, 2027, for Nucynta and December 27, 2025, for Nucynta ER. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

**Item 9.01 Financial Statements and Exhibits.**

| | |
|---|---|
| 99.1 | Press Release, dated June 13, 2024 |
| 104 | Cover Page Interactive Data File (embedded within the 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.

Dated: June 13, 2024

Collegium Pharmaceutical, Inc.

By: /s/ Colleen Tupper
Name: Colleen Tupper
Title: Executive Vice President and Chief Financial Officer

**Exhibit 99.1**

**Collegium Obtains Six Month Extension of U.S. Pediatric Exclusivity for Nucynta Franchise**

**STOUGHTON, Mass., June 13, 2024 --** Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today announced that the U.S. Food and Drug Administration (FDA) has granted pediatric exclusivity for Nucynta® and Nucynta® ER ("the Nucynta Franchise"). In 2023, FDA granted New Patient Population exclusivity for Nucynta in pediatrics, extending the period of U.S. exclusivity from June 27, 2025, to July 3, 2026. FDA's grant of pediatric exclusivity now extends exclusivity of the Nucynta Franchise an additional six months, to January 3, 2027, for Nucynta and December 27, 2025, for Nucynta ER.

"We are pleased with FDA's grant of pediatric exclusivity for the Nucynta Franchise," said Thomas Smith, M.D., Collegium's Chief Medical Officer. "This grant of pediatric exclusivity enhances the value of the Nucynta franchise and bolsters our near-term outlook. Collegium is proud to lead with science in support of people living with serious medical conditions and the communities we serve."

Nucynta is currently approved in the U.S. for the management of acute pain severe enough to require an opioid analgesic, in light of the known risks associated with opioid analgesic use, and for which alternative treatments are inadequate in adults and pediatric patients aged six years and older with a body weight of at least 40 kg.

Nucynta ER is currently approved in the U.S. for the management of severe and persistent pain in adults that requires an extended treatment period with a daily opioid analgesic, in light of the known risks associated with opioid analgesic use, and for which alternative treatment options are inadequate, and severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Please see Important Safety Information that follows below and complete product information, including the Boxed Warning, available at www.NUCYNTA.com.

**About Collegium Pharmaceutical, Inc.**

Collegium is a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit the Company's website at www.collegiumpharma.com.

**NUCYNTA® (tapentadol) INDICATIONS AND USAGE**

**NUCYNTA® (tapentadol) tablets are:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short term (acute) pain in adults and children 6 years of age and older who weigh at least 88 pounds (40 kg), when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.

- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.

**IMPORTANT SAFETY INFORMATION ABOUT NUCYNTA TABLETS**

**WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA TABLETS**

Addiction, Abuse, and Misuse
**Because the use of NUCYNTA tablets exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess regularly for the development of these behaviors and conditions.**

Life-Threatening Respiratory Depression
**Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA tablets, especially during initiation of NUCYNTA tablets or following a dose increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA tablets are essential.**

Accidental Ingestion
**Accidental ingestion of even one dose of NUCYNTA tablets, especially by children, can result in a fatal overdose of tapentadol.**

Risks From Concomitant Use With Benzodiazepines or Other CNS Depressants
**Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of NUCYNTA tablets and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.**

Neonatal Opioid Withdrawal Syndrome
**If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of Neonatal Opioid Withdrawal Syndrome which may be life threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.**

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)
**Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.**

**Important information about NUCYNTA tablets:**

- **Get emergency help or call 911 right away if you take too much NUCYNTA (overdose) tablets.** When you first start taking NUCYNTA tablets, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.

- Taking NUCYNTA tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA tablets. They could die from taking it. Selling or giving away NUCYNTA tablets is against the law.
- Store NUCYNTA tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

**Do not take NUCYNTA tablets if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

**Before taking NUCYNTA tablets, tell your healthcare provider if you have a history of:**

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose or mental health problems
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

**Tell your healthcare provider if you:**

- **notice your pain getting worse.** If your pain gets worse after you take NUCYNTA tablets, do not take more NUCYNTA tablets without first talking to your healthcare provider. Tell your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking NUCYNTA tablets.
- **are pregnant or planning to become pregnant.** Use of NUCYNTA tablets for an extended period of time during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **are breastfeeding.** NUCYNTA tablets pass into breast milk and may harm your baby.
- are living in a household where there are small children or someone who has abused street or prescription drugs.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA tablets with certain other medicines can cause serious side effects that could lead to death.

**When taking NUCYNTA tablets:**

- Do not change your dose. Take NUCYNTA tablets exactly as prescribed by your healthcare provider.
- Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take NUCYNTA tablets for a few days. You may have some NUCYNTA tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused NUCYNTA tablets.

- Take your prescribed dose every 4-6 hours, at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NUCYNTA tablets regularly, do not stop taking NUCYNTA tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused NUCYNTA Tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

**While taking NUCYNTA tablets, DO NOT:**

- Drive or operate heavy machinery, until you know how NUCYNTA tablets affect you. NUCYNTA tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with NUCYNTA tablets may cause you to overdose and die.

**The possible side effects of NUCYNTA tablets:**

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

**Get emergency medical help or call 911 right away if you have:**

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all of the possible side effects of NUCYNTA tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information, go to dailymed.nlm.nih.gov.

**See full Prescribing Information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, and the Medication Guide accompanying this piece or at Nucynta.com/IRpi. Speak to your healthcare provider if you have questions about Nucynta.**

**NUCYNTA® ER (tapentadol) INDICATIONS AND USAGE**

**NUCYNTA® ER (tapentadol) extended-release tablets are:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain in adults that requires an extended treatment period with a daily opioid pain medicine, when other pain medicines do not treat your pain well enough or you cannot tolerate them.
- Also used in adults to manage severe and persistent pain from damaged nerves (neuropathic pain) that happens with diabetes, and that requires an extended treatment period with a daily opioid pain medicine, when other pain medicines do not treat your pain well enough or you cannot tolerate them.

- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not to be taken on an “as needed” basis.

**IMPORTANT SAFETY INFORMATION ABOUT NUCYNTA ER**

**WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA ER**

Addiction, Abuse, and Misuse

**Because the use of NUCYNTA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient’s risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.**

Life-Threatening Respiratory Depression

**Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA ER, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA ER are essential. Instruct patients to swallow NUCYNTA ER tablets whole; crushing, chewing, or dissolving NUCYNTA ER tablets can cause rapid release and absorption of a potentially fatal dose of tapentadol.**

Accidental Ingestion

**Accidental ingestion of even one dose of NUCYNTA ER, especially by children, can result in a fatal overdose of tapentadol. Interaction With Alcohol Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while taking NUCYNTA ER. The co-ingestion of alcohol with NUCYNTA ER may result in increased plasma tapentadol levels and a potentially fatal overdose of tapentadol.**

Risks From Concomitant Use With Benzodiazepines or Other CNS Depressants

**Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of NUCYNTA ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.**

Neonatal Opioid Withdrawal Syndrome (NOWS)

**If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.**

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

**Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.**

**Important information about NUCYNTA ER:**

- **Get emergency help or call 911 right away if you take too much NUCYNTA ER (overdose).** When you first start taking NUCYNTA ER, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NUCYNTA ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA ER. They could die from taking it. Selling or giving away NUCYNTA ER is against the law.
- Store NUCYNTA ER securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

**Do not take NUCYNTA ER if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

**Before taking NUCYNTA ER, tell your healthcare provider if you have a history of:**

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose or mental health problems
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

**Tell your healthcare provider if you:**

- notice your pain getting worse. If your pain gets worse after you take NUCYNTA ER, do not take more of NUCYNTA ER without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking NUCYNTA ER.
- **are pregnant or planning to become pregnant.** Use of NUCYNTA ER for an extended period of time during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **are breastfeeding.** Not recommended during treatment with NUCYNTA ER. It may harm your baby.
- are living in a household where there are small children or someone who has abused street or prescription drugs.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA ER with certain other medicines can cause serious side effects.

**When taking NUCYNTA ER:**

- Do not change your dose. Take NUCYNTA ER exactly as prescribed by your healthcare provider. Use the lowest effective dose for the shortest time needed.
- Take your prescribed dose every 12 hours, at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time.
- Swallow NUCYNTA ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject NUCYNTA ER because this may cause you to overdose and die.
- Call your healthcare provider if the dose you are taking does not control your pain.
- Do not stop taking NUCYNTA ER without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused NUCYNTA ER by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

**While taking NUCYNTA ER, DO NOT:**

- Drive or operate heavy machinery until you know how NUCYNTA ER affects you. NUCYNTA ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with NUCYNTA ER may cause you to overdose and die.

**The possible side effects of NUCYNTA ER are:**

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

**Get emergency medical help or call 911 right away if you have:**

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- agitation, hallucinations, coma, feeling overheated, or heavy sweating.

These are not all the possible side effects of NUCYNTA ER. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov.

**See full Prescribing Information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, accompanying this piece or at Nucynta.com/ERpi. Speak to your healthcare provider if you have questions about Nucynta ER.**

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "forecasts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements related to current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from the company's current expectations, including risks relating to, among others: unknown liabilities; risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; our ability to commercialize and grow sales of our products; our ability to manage our relationships with licensors; the success of competing products that are or become available; our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of our products; the size of the markets for our products, and our ability to service those markets; our ability to obtain reimbursement and third-party payor contracts for our products; the rate and degree of market acceptance of our products; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement or other litigation that may be brought by or against us; the outcome of any governmental investigation related to our business; our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and manufacture adequate supplies of commercially saleable inventory; our ability to obtain funding for our operations and business development; regulatory developments in the U.S.; our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance; our customer concentration; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. These and other risks are described under the heading "Risk Factors" in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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