
**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 2, 2021**

COLLEGIUM PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Virginia
(State or Other Jurisdiction
of Incorporation or Organization)

001-37372
(Commission File Number)

03-0416362
(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 7.01 Regulation FD Disclosure.

On June 2, 2021, Collegium Pharmaceutical, Inc. delivered a corporate presentation at the Jefferies Healthcare Conference. A copy of the presentation is attached hereto as Exhibit 99.1 and is being furnished, not filed, under Item 7.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

[99.1 Corporate presentation, dated June 2, 2021.](#)

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 2, 2021

Collegium Pharmaceutical, Inc.

By: /s/ Colleen Tupper

Name: Colleen Tupper

Title: Executive Vice President and Chief Financial Officer

Collegium Pharmaceutical, Inc. Corporate Overview

June 2021



Forward-Looking Statements

This presentation 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 presentation include, among others, statements regarding financial guidance for Xtampza ER and Nucynta Franchise revenues, Adjusted EBITDA, total operating expenses, current and future market opportunities for our products and our assumptions related thereto. 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. Management's expectations and, therefore, any forward-looking statements in this presentation could also be affected by risks and uncertainties relating to a number of other factors, including the impact of the COVID-19 pandemic on our ability to conduct our business, reach our customers, and supply the market with our 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 obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product; the size of the markets for our products and product candidates, 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 and product candidates; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P.; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and other filings with the SEC. Any forward-looking statements that we make in this presentation speak only as of the date of this presentation. 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 presentation.

This company presentation is not for promotional purposes.



Our Mission:
**We are committed to being the leader
in responsible pain management**

We are a mission-driven organization with an **unwavering commitment** to people living with pain and the communities we serve

Integrity is Core to our Mission



The core of our mission, and the central tenet of our values, is
leading with integrity.

As an organization committed to being the leader in responsible pain management, we believe that **integrity begins with the equitable, inclusive and dynamic environment we create within our organization**, and manifests in all of our corporate activities, which we are committed to conducting at all times in compliance with both the letter and the spirit of the laws, regulations and policies that govern us.

Experienced Management Team & Board of Directors



Joseph Ciaffoni
President, CEO &
Board Member



Alison Fleming, Ph.D.
EVP & Chief Technical Officer
Inventor of DETERx®



Colleen Tupper
EVP & Chief
Financial Officer



Richard Malamut, M.D.
EVP & Chief Medical Officer



Scott Dreyer
EVP & Chief
Commercial Officer



Shirley Kuhlmann
EVP & General Counsel



Bart Dunn
EVP, Strategy &
Corporate Development



Collegium Board of Directors

Joseph Ciaffoni
President & CEO,
Collegium Pharmaceutical

Michael Heffernan
Chairman of the Board &
Collegium Founder

Garen Bohlin
Former COO, Sirtris,
Former CEO, Syntonix

John Fallon, M.D.
Former SVP & CMO,
Blue Cross Blue Shield of MA

Gwen Melincoff
Former Senior BD roles, BTG
International, Shire, Adolor

John Freund, M.D.
Co-Founder & Partner,
Skyline Ventures

Gino Santini
Former SVP, Corp. Strategy & BD,
President, Eli Lilly

Rita Balice-Gordon
Chief Scientific Officer,
Muna Therapeutics

Strong Corporate Culture

Commitment to our Core Values and DE&I



- Uphold Integrity
- Embrace Differences
- Encourage Expression
- Be Accountable

External Recognition of our Culture



Corporate Social Responsibility Efforts



Our Strategy

Deliver on our mission | Create value for shareholders



**Maximize the value of
our differentiated
portfolio of pain
products**



**Achieve our near-term
operational and
financial goals**



**Invest in our long-term
growth**

Focus on 2021 Objectives



**Drive revenue growth
from Xtampza® ER**



**Achieve stable profit
contributions from
Nucynta® franchise**



**Leverage current cost
structure, generate cash**



**Deploy balance sheet
in disciplined manner**



**Seek opportunities to
enhance portfolio long-term**

Addressing a Need for Differentiated Pain Products



~50M Americans experience some form of chronic or severe disabling pain.¹



Chronic pain leads to over \$560 billion in healthcare and productivity costs each year.²



The FDA has encouraged development of prescription opioids with abuse-deterrent formulations.³



HCPs and regulators are advocating for appropriate opioid prescribing practices that may help mitigate the risk of addiction and other adverse events to patients.

Sources: 1. Yong RJ, Mullins PM, Bhattacharyya N. The prevalence of chronic pain among adults in the United States. *Pain*. 2021; epub ahead of print. April 2021.
2. Gaskin DJ, Richard P. The Economic Costs of Pain in the United States. In: Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington (DC): National Academies Press (US); 2011. Appendix C.
3. Center for Drug Evaluation and Research (CDER). Guidance for industry: abuse-deterrent opioids — evaluation and labeling. Rockville, MD: U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. <https://www.fda.gov/files/drugs/published/Abuse-Deterrent-Opioids-Evaluation-and-Labeling.pdf> Published April 2015. Accessed January 4, 2021.

Our Differentiated Pain Portfolio

Viewed Favorably by HCPs & Strong Intent to Prescribe¹

LABEL & ACCESS DIFFERENTIATION



- Extended-release, oral oxycodone
- Indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate; not for PRN use²
- Abuse-deterrent label²; proprietary formulation
- Broad formulary coverage, strong position

PRODUCT DIFFERENTIATION



- Extended-release and immediate-release formulations of the opioid tapentadol with different indications
- ER formulation proven to treat chronic low back pain and neuropathic pain associated with DPN in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate; not for PRN use³
- IR formulation is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults⁴

Boxed Warning: Xtampza® ER, Nucynta® and Nucynta® ER exposes patients and other users to the risks of opioid addiction, abuse and misuse, which can lead to overdose and death. Serious, life-threatening, or fatal respiratory depression may occur. Accidental ingestion, especially by children, can result in fatal overdose. The Prescribing Information includes information on other Boxed Warnings and serious side effects.

Abuse of Xtampza® ER by injection and by the oral and nasal routes of administration is still possible.

10 Note: Xtampza® ER, DETERx®, and Nucynta® are registered trademarks of Collegium Pharmaceutical, Inc.
Sources: 1. ATU (Awareness, Trial, & Usage) Market Research Study, fielded Q1 2021. 2. Xtampza® ER [package insert]. Stoughton, MA: Collegium Pharmaceutical Inc.; 2021. 3. Nucynta® ER [package insert]. Stoughton, MA: Collegium Pharmaceutical Inc.; 2021. 4. Nucynta® [package insert]. Stoughton, MA: Collegium Pharmaceutical Inc.; 2021



EFFICACY

 <p>Powerful Pain Relief of ER Oxycodone</p>	 <p>12-Hour Dosing</p>
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DIFFERENTIATED LABEL VS. OXYCONTIN®

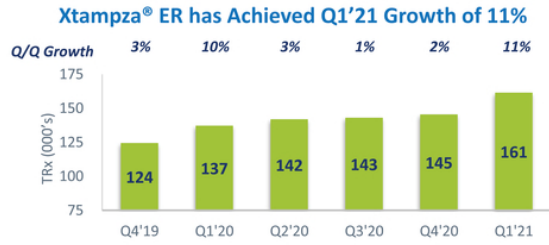
 <p>Comparative PK Data Versus OxyContin®¹</p>	 <p>Maintains PK Profile Designed to maintain its PK profile even when manipulated¹</p>
 <p>Abuse-Deterrent Labeling Only ER oxycodone with labelling for abuse-deterrence via all 3 routes: oral, intranasal, and intravenous^{1,2,3}</p>	 <p>DETERx® Technology Only opioid w/ unique DETERx® abuse-deterrent technology engineered to resist: crushing, grinding, cutting, chewing and injecting¹</p>

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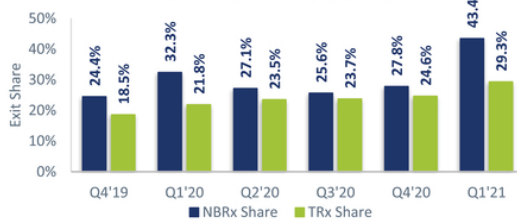
Abuse of Xtampza® ER by injection and by the oral and nasal routes of administration is still possible. Additional data, including epidemiological data, may provide further information on the impact of the current formulation of Xtampza® ER on the abuse liability of the drug.

11 Sources: 1. Xtampza® ER [package insert]. Stoughton, MA: Collegium Pharmaceutical Inc.; 2021. 2. OxyContin [package insert]. Stamford, CT: Purdue Pharma LP; 2021. 3. Oxycodone Hydrochloride tablet, film coated, extended release [package insert]. Parsippany, NJ: Teva Pharmaceuticals, USA, Inc.; 2021. OxyContin is a registered trademark of Purdue Pharma LP

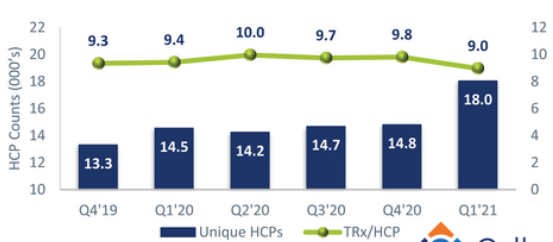
Xtampza® ER: Immediate Acceleration in 2021



Significant NBRx Share Acceleration Q1'21 Will Drive Continued Growth of TRx Share^{1,2}



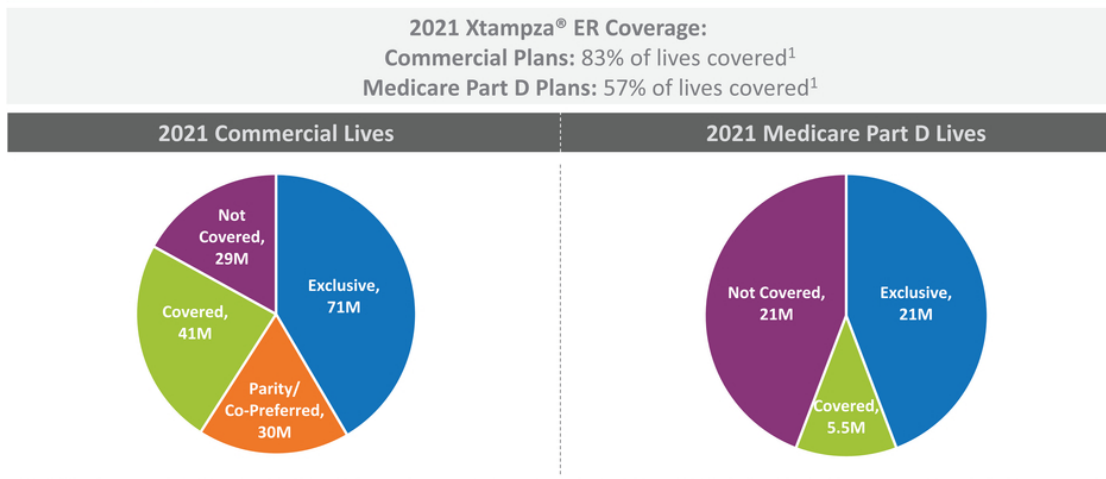
Xtampza® ER Unique Prescribers Were up 22% in Q1'21^{1,3}



12 Sources: 1: IQVIA Weekly Xponent Prescribing Dynamics through Apr 2, 2021; 2: IQVIA NPA Monthly through Mar 2021; 3: IQVIA Monthly Xponent through Mar 2021
 +Note: All historical data has been updated and is sourced with IQVIA Data Enhancements; Branded ER Market Data



2021 Xtampza® ER Growth Supported by Broad Market Access Coverage



Xtampza® ER is covered through Exclusive & Parity Contracts for ~55% of lives in 2021¹

13 Sources: 1: MMIT Xtampza® ER data April 2021; policies applied
 Graph Data Source: MMIT Xtampza® ER data accessed April 26, 2021; policies applied
 Note: Total commercial insured population approximately 171 million lives; Total Medicare part D insured population approximately 47.5 million lives



Xtampza® ER Positioned for Next Phase of Growth

Goal for Xtampza® ER:

- Secure path for Xtampza® ER market leadership
- Expect to emerge as #1 branded product in 2023

Strong patent position supports long commercial runway:

- 19 OB listed patents going out to 2036
- TEVA ANDA litigation settled for September 2033
- No approved ANDA for Xtampza® ER to date

Managing Nucynta® Franchise for Stable Profit Contribution

Goal for the Nucynta® Franchise:

- Contribute stable profits through remaining 5-year lifecycle
- Leverage our cost structure

Five-year commercial runway:

- IP through mid-2025
- Potential pediatric extension would extend exclusivity through end of 2025

Strengthening Our Financial Position

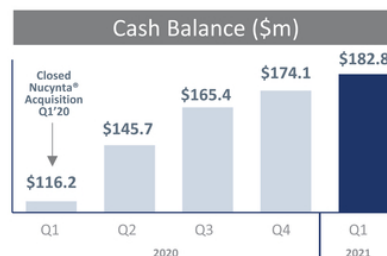
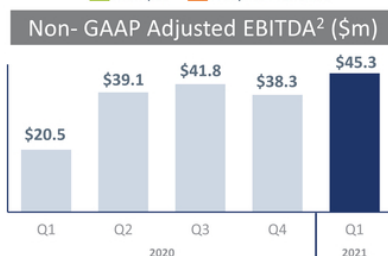
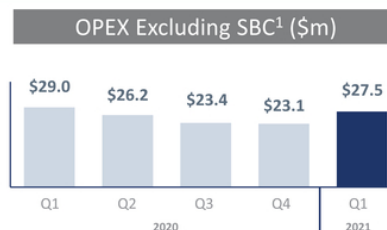
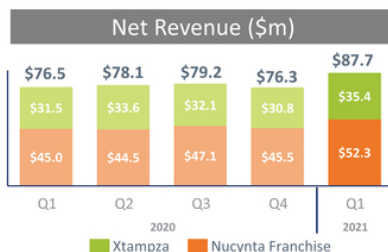
Key Highlights

Record Net Revenue of \$87.7m in Q1'21

Reduced Operating Expenses, Excluding Stock-Based Comp, by 5% in Q1'21 vs. Q1'20

GAAP Net Income of \$15.7m in Q1'21

Adjusted EBITDA of \$45.3m in Q1'21



Notes: This financial data, provided by Collegium Pharmaceutical, Inc. in its Quarterly Report on Form 10-Q filed with the SEC on May 6, 2021.

1. OPEX Excluding SBC is defined as Operating Expenses less Stock-Based Compensation Expense

2. Non-GAAP Adjusted EBITDA excludes stock-based compensation, non-cash interest and non-cash amortization of the Nucynta® intangible asset. The company has not provided a reconciliation of its full-year 2021 guidance for non-GAAP adjusted income (loss) to the most directly comparable forward-looking GAAP measure because it is unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation. These items are uncertain and depend on various factors that could have a material impact on GAAP net income (loss) for the guidance period.

2021: Focused on Growth & Value Creation

Deliver on our mission | Create value for shareholders



OUR STRATEGY

Maximize the value of our differentiated portfolio of pain products



Achieve our near-term operational and financial goals



Invest in our long-term growth

2021 FOCUS

- Drive revenue growth from Xtampza® ER
- Stable Nucynta® Franchise profit contributions

- Leverage our current cost structure
 - Revenue growth
 - Profitability
 - Cash generation

- Deploy balance sheet in a disciplined manner
- Actively seek opportunities to enhance portfolio long-term

Disciplined Approach to Business Development

Favorable position with current in-line portfolio

- Long runway with Xtampza® ER: 19 OB listed patents through 2036
- Stable Profit Contributions from the Nucynta® Franchise through 2025

Strong balance sheet creates flexibility

- \$174m cash balance YE2020
- \$170-180m Non-GAAP Adjusted EBITDA 2021 guidance^{1,2}



Actively pursuing opportunities to enhance portfolio long-term

Priority 1

- Novel non-opioid pain assets
- Ph 2 assets with potential to generate revenue in 2025-2027 timeframe
- Peak sales potential of \$150m+

Priority 2

- Differentiated commercial-stage pain assets
- Leverage cost structure & accrete within 24 mos or less

1: This financial guidance, provided by Collegium Pharmaceutical, Inc. in its Current Report on Form 8-K filed with the SEC on January 6, 2021, and updated on the Q1 2021 Earnings Press Release issued May 6, 2021, is effective only as of this date. The company expressly disclaims any obligation to update or reaffirm guidance. The company only provides guidance in a Regulation FD compliant manner.

18 2: Non-GAAP Adjusted EBITDA excludes stock-based compensation, non-cash interest and non-cash amortization of the Nucynta® intangible asset. The company has not provided a reconciliation of its full-year 2021 guidance for non-GAAP adjusted income (loss) to the most directly comparable forward-looking GAAP measure because it is unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation. These items are uncertain and depend on various factors that could have a material impact on GAAP net income (loss) for the guidance period.



2021 Financial Guidance¹

Xtampza[®] ER Revenue	\$155.0 - \$165.0 Million	Nucynta[®] Franchise Revenue	\$185.0 - \$195.0 Million
Total Operating Expenses	\$125.0 - \$135.0 Million	Non-GAAP Adjusted EBITDA²	\$170.0 - \$180.0 Million

Notes

1: This financial guidance, provided by Collegium Pharmaceutical, Inc. in its Current Report on Form 8-K filed with the SEC on January 6, 2021, and updated on the Q1 2021 Earnings Press Release issued May 6, 2021, is effective only as of this date. The company expressly disclaims any obligation to update or reaffirm guidance. The company only provides guidance in a Regulation FD compliant manner.

2: Non-GAAP Adjusted EBITDA excludes stock-based compensation, non-cash interest and non-cash amortization of the Nucynta[®] intangible asset. The company has not provided a reconciliation of its full-year 2021 guidance for non-GAAP adjusted income (loss) to the most directly comparable forward-looking GAAP measure because it is unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation. These items are uncertain and depend on various factors that could have a material impact on GAAP net income (loss) for the guidance period.

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