
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 5, 2020

COLLEGIUM PHARMACEUTICAL, INC.

(Exact name of registrant as specified in its charter)

Virginia
(state or other jurisdiction
of incorporation)

001-37372
(Commission
File Number)

03-0416362
(I.R.S. Employer
Identification No.)

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

02072
(Zip Code)

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

(Former name or former address, if changed since last report)

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))

Indicated 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.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common stock, par value \$0.001 per share	COLL	The NASDAQ Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On August 5, 2020, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended June 30, 2020. The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and is being furnished, not filed, under Item 2.02 of this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 5, 2020.
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.

Collegium Pharmaceutical, Inc.

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

Dated: August 5, 2020



Collegium Reports Net Income of \$8.1 Million in the Second Quarter of 2020

– Non-GAAP Net Income of \$33.2 Million in the Second Quarter of 2020 –

– Generated \$43.9 Million in Cash from Operating Activities in the Second Quarter of 2020 –

– Xtampza[®] ER Net Revenue Increased 29% over the Prior Year Period –

– Conference Call Scheduled for Today at 4:30 p.m. ET –

STOUGHTON, Mass., August 5, 2020 -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a specialty pharmaceutical company committed to being the leader in responsible pain management, today reported its financial results for the second quarter ended June 30, 2020 and provided a corporate update.

“Collegium delivered strong financial results in the second quarter of 2020, which is a testament to the resilience and adaptability of our people and operations,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “We made progress towards achieving each of our key business objectives, while prioritizing the health and safety of our people, customers and communities. Xtampza ER revenue growth and the impact of the Nucynta acquisition generated meaningful cashflow from operations, enabling us to begin to pay down debt, and setting the stage for 2020 to be a financially transformative year for Collegium.”

Recent Business Highlights

- Xtampza ER total prescriptions grew to 141,678 for the quarter ended June 30, 2020 (the “2020 Quarter”), representing a 22% increase over the quarter ended June 30, 2019 (the “2019 Quarter”) and a 4% increase over the first quarter of 2020.
- Xtampza ER market share of the oxycodone extended-release market was 23.5% in the 2020 Quarter, up from 21.8% in the first quarter of 2020.
- In the 2020 Quarter, two new formulation patents covering Xtampza ER were added to the FDA Orange Book, one with an expiry in 2030 and one with an expiry in 2036. With these recent additions to the patent estate, Xtampza ER is now covered by 19 Orange Book-listed patents.
- A manuscript describing certain real-world evidence with respect to abuse, misuse, and diversion of Xtampza ER was recently accepted for publication in *Pain Medicine*, the Journal of the American Academy of Pain Medicine.
- Nucynta[®] ER market share of the branded extended-release market grew to 6.2% in the 2020 Quarter, up from 6.1% in the first quarter of 2020. This represents five consecutive quarters in which market share was stable or growing.

Financial Results for Quarter Ended June 30, 2020

- Xtampza ER net product revenues were \$33.6 million for the 2020 Quarter, compared to \$26.0 million for the 2019 Quarter and \$31.5 million for the quarter ended March 31, 2020, representing an increase of 29% and 7%, respectively.
 - Nucynta franchise net product revenues were \$44.5 million in the 2020 Quarter, compared to \$49.0 million for the 2019 Quarter and \$45.0 million for the quarter ended March 31, 2020, representing a decrease of 9% and 1%, respectively.
 - Operating expenses were \$31.8 million for the 2020 Quarter, compared to \$31.4 million for the 2019 Quarter.
 - Net income for the 2020 Quarter was \$8.1 million, or \$0.23 per share (basic and diluted), compared to net loss of \$4.7 million, or \$0.14 loss per share (basic and diluted), for the 2019 Quarter.
 - Non-GAAP adjusted income for the 2020 Quarter was \$33.2 million, compared to a non-GAAP adjusted income of \$3.1 million for the 2019 Quarter.
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Conference Call Information

The Company will host a conference call and live audio webcast on Wednesday, August 5, 2020 at 4:30 p.m. Eastern Time. To access the conference call, please dial (877) 407-8037 (U.S.) or (201) 689-8037 (International) and reference the "Collegium Q2 Earnings Call." An audio webcast will be accessible from the Investors section of the Company's website: www.collegiumpharma.com. The webcast will be available for replay on the Company's website approximately two hours after the event.

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.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we have included information about non-GAAP adjusted income. We use this non-GAAP financial measure to understand, manage and evaluate the Company as we believe it represents the performance of our core business. Because this non-GAAP financial measure is an important internal measure for the Company, we believe that the presentation of the non-GAAP financial measure provides analysts, investors and lenders insight into management's view and assessment of the Company's ongoing operating performance. In addition, we believe that the presentation of this non-GAAP financial measure, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing the Company's performance and results from period to period. We report this non-GAAP financial measure in order to portray the results of our major operations prior to considering certain income statement elements. This non-GAAP financial measure should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

Non-GAAP adjusted income is not based on any standardized methodology prescribed by GAAP and represents GAAP net income adjusted to exclude stock-based compensation expense, amortization expense, non-cash interest expense, certain royalty costs recognized in connection with the Nucynta Commercialization Agreement and the provision for income taxes. Any non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, a non-GAAP measure used by other companies. Please see the section of this press release titled "Reconciliation of GAAP to Non-GAAP Financial Information" for a reconciliation of non-GAAP adjusted income to its most directly comparable GAAP measure.

The Company has not provided a reconciliation of its full-year 2020 guidance for non-GAAP adjusted income 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 such a reconciliation. These items are uncertain and depend on various factors that could have a material impact on GAAP net income for the guidance period.

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 regarding financial guidance for Xtampza ER and Nucynta Franchise revenues, 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 press release 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. and Teva Pharmaceuticals USA, Inc.; the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications; 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 June 30, 2020 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.

Contact:

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Collegium Pharmaceutical, Inc.

Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	<u>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Cash and cash equivalents	\$ 145,678	170,019
Accounts receivable	81,195	72,953
Inventory	18,815	9,643
Prepaid expenses and other current assets	5,125	3,105
Property and equipment, net	15,156	11,854
Operating lease assets	8,697	9,047
Intangible asset, net	369,494	29,503
Restricted cash	2,547	—
Other noncurrent assets	163	178
Total assets	\$ 646,870	\$ 306,302
Accounts payable and accrued expenses	33,293	39,727
Accrued rebates, returns and discounts	171,053	157,549
Term notes payable	180,931	11,500
Convertible senior notes	96,046	—
Operating lease liabilities	9,780	10,094
Stockholders' equity	155,767	87,432
Total liabilities and stockholders' equity	\$ 646,870	\$ 306,302

Collegium Pharmaceutical, Inc.

Unaudited Condensed Statements of Operations
(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Product revenues, net	\$ 78,058	\$ 75,040	\$ 154,569	\$ 149,556
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	12,899	44,966	40,128	90,442
Intangible asset amortization	16,795	3,688	27,090	7,376
Total cost of products revenues	29,694	48,654	67,218	97,818
Gross profit	48,364	26,386	87,351	51,738
Operating expenses				
Research and development	2,493	2,459	5,159	5,451
Selling, general and administrative	29,322	28,935	60,582	61,287
Total operating expenses	31,815	31,394	65,741	66,738
Income (loss) from operations	16,549	(5,008)	21,610	(15,000)
Interest expense	(8,259)	(236)	(13,082)	(470)
Interest income	14	532	226	1,058
Income (loss) before income taxes	8,304	(4,712)	8,754	(14,412)
Provision for income taxes	246	—	246	—
Net income (loss)	\$ 8,058	\$ (4,712)	\$ 8,508	\$ (14,412)
Earnings (loss) per share — basic	\$ 0.23	\$ (0.14)	\$ 0.25	\$ (0.43)
Weighted-average shares — basic	34,395,266	33,397,709	34,247,977	33,338,243
Earnings (loss) per share — diluted	\$ 0.23	\$ (0.14)	\$ 0.24	\$ (0.43)
Weighted-average shares — diluted	35,091,906	33,397,709	35,089,740	33,338,243

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)
(unaudited)

	Three months ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
GAAP net income (loss)	\$ 8,058	\$ (4,712)	\$ 8,508	\$ (14,412)
Non-GAAP adjustments:				
Stock-based compensation expense ⁽¹⁾	5,584	4,162	10,535	8,425
Intangible asset amortization ⁽²⁾	16,795	3,688	27,090	7,376
Non-cash interest expense ⁽³⁾	2,524	—	3,860	—
Nucynta royalty adjustment ⁽⁴⁾	—	—	14,216	—
Provision for income taxes ⁽⁵⁾	246	—	246	—
Total non-GAAP adjustments	\$ 25,149	\$ 7,850	\$ 55,947	\$ 15,801
Non-GAAP adjusted income	\$ 33,207	\$ 3,138	\$ 64,455	\$ 1,389

- (1) Represents stock-based compensation expense associated with our stock option, restricted stock unit and performance stock unit grants and our employee share purchase plan.
- (2) Represents amortization expense from the Nucynta Intangible Asset.
- (3) Represents non-cash interest expense recognized related to the accretion of debt discount and amortization of debt issuance costs.
- (4) Represents non-recurring adjustment for royalty expense recognized in 2020 prior to the closing of the Nucynta Asset Purchase Agreement in February 2020. The royalty expense was included as a reduction to the base purchase price for the Nucynta Asset Purchase Agreement and, upon closing, the Company was discharged of any unpaid royalties due to Assertio.
- (5) Represents current provision for estimated income taxes.