
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 7, 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:

| 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 |

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2020, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended March 31, 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 May 7, 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: May 7, 2020



Collegium Reports First Quarter 2020 Profitability

– Achieves GAAP Profitability with \$0.5 Million in Net Income in the First Quarter of 2020 –

– Non-GAAP Net Income of \$31.2 Million in the First Quarter of 2020 –

– Xtampza® ER Prescriptions Grew 30% Over the First Quarter of 2019 –

– Collegium Updates 2020 Guidance to Reflect COVID-19 Impact –

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

STOUGHTON, Mass., May 7, 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 first quarter ended March 31, 2020 and provided a corporate update.

“The COVID-19 pandemic presents complex challenges to individuals, organizations and communities across the world. At Collegium, we are committed to keeping our employees safe, reliably supplying our medicines and supporting our customers and the communities we serve,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “Despite the unprecedented times we all face, we continue to make progress towards our mission of becoming the leader in responsible pain management. I am honored and humbled to work alongside our dedicated employees who are committed to making a difference in the lives of people suffering from pain.”

“In the first quarter of 2020 Collegium achieved profitability, driven by Xtampza ER revenue growth and the closing of the Nucynta franchise acquisition,” commented Paul Brannelly, Executive Vice President and Chief Financial Officer of Collegium. “Despite the impacts of COVID-19, we expect 2020 will be financially transformative for Collegium, with a focus on profitability, cash generation and debt repayment.”

Recent Business Highlights

- Xtampza ER total prescriptions grew to 136,736 for the quarter ended March 31, 2020 (the “2020 Quarter”), representing a 30% increase over the quarter ended March 31, 2019 (the “2019 Quarter”) and a 10.2% increase over the fourth quarter of 2019.
- Xtampza ER market share of the oxycodone extended-release market was 21.8% in the 2020 Quarter, up from 18.5% in the fourth quarter of 2019.
- The number of unique prescribers grew to 14,600 in the 2020 Quarter, a 9.5% increase over the fourth quarter of 2019.
- In the 2020 Quarter, two new patents covering Xtampza ER were added to the FDA Orange Book. With these recent additions to the patent estate, Xtampza ER is now covered by 17 Orange Book listed patents.
- The Company saw strong volume and market share growth in the 20 new exclusive ER oxycodone formulary wins, covering more than 35 million lives for Xtampza ER, that took effect January 1, 2020. Collegium is the exclusive ER oxycodone for approximately 40% of Commercial and Part D covered lives. Xtampza ER continues to have broad-based coverage, including 95% coverage of Commercial lives and 50% coverage of Part D lives.
- Nucynta® ER market share of the branded extended-release market grew to 6.1% in the 2020 Quarter, up from 5.8% in the fourth quarter of 2019. This represents four consecutive quarters in which market share grew or was stable.
- On February 13, 2020, the Company closed the acquisition of the U.S. rights to the Nucynta Franchise from Assertio Therapeutics, Inc.

Financial Guidance for 2020

The Company updates its full-year 2020 financial guidance:

| | <u>Prior</u> | <u>Updated</u> |
|----------------------------|----------------------------|----------------------------|
| Xtampza ER Revenues | \$150.0 to \$160.0 million | \$130.0 to \$140.0 million |
| Nucynta Franchise Revenues | \$170.0 to \$180.0 million | Unchanged |
| Total Operating Expenses | \$130.0 to \$140.0 million | \$120.0 to \$130.0 million |
| Non-GAAP Adjusted Income | \$125.0 to \$140.0 million | \$125.0 to \$135.0 million |

Financial Results for Quarter Ended March 31, 2020

- Xtampza ER net product revenues were \$31.5 million for the 2020 Quarter, compared to \$25.1 million for the 2019 Quarter and \$27.4 million for the quarter ended December 31, 2019, representing an increase of 25% and 15%, respectively.
- Nucynta franchise net product revenues were \$45.0 million in the 2020 Quarter, compared to \$49.4 million for the 2019 Quarter and \$46.8 million for the quarter ended December 31, 2019, representing a decrease of 9% and 4%, respectively.
- Operating expenses were \$33.9 million for the 2020 Quarter, compared to \$35.3 million for the 2019 Quarter.
- Net income for the 2020 Quarter was \$0.5 Million, or \$0.01 per share (basic and diluted), compared to net loss of \$9.7 million, or \$0.29 loss per share (basic and diluted), for the 2019 Quarter. In the 2020 Quarter, in relation to the accounting treatment of the Nucynta Acquisition, net income includes a one-time expense of \$14.2 million for royalties that would have been owed under the prior Nucynta commercialization agreement.
- Non-GAAP adjusted income for the 2020 Quarter was \$31.2 million, compared to a non-GAAP adjusted loss of \$1.7 million for the 2019 Quarter.

Collegium's Response to COVID-19

In response to the ongoing COVID-19 pandemic, and in an effort to ensure the health and wellbeing of our employees, customers, stakeholders and communities, the Company has taken the following actions:

- Implemented a mandatory work-from-home policy for the entire organization, including our home-office and field-based employees.
- Created a cross-functional pandemic planning team focused on ensuring the health and well-being of our employees and customers and ensuring preparedness plans for when we resume in-person activities.
- Confirmed the stability of our supply chain and worked with our manufacturing partners to ensure strong business continuity plans.
- Donated \$240,000 to support community response efforts, including \$40,000 which was raised through the Company's employer match program.

Conference Call Information

The Company will host a conference call and live audio webcast on Thursday, May 7, 2020 at 4:30 p.m. Eastern Time. To access the conference call, please dial (888) 698-6931 (U.S.) or (805) 905-2993 (International) and refer to Conference ID: 358-1447. 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 (loss). 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 (loss) is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) adjusted to exclude stock-based compensation expense, amortization expense, non-cash interest expense, and certain royalty costs recognized in connection with the Nucynta Commercialization Agreement. 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 loss 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 (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 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.

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 expectations related to the potential impact of the Nucynta acquisition on our future operating results; 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 Annual Report on Form 10-K for the year ended December 31, 2019 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>March 31,</u> <u>2020</u> | <u>December 31,</u> <u>2019</u> |
|---|---------------------------------|------------------------------------|
| Cash and cash equivalents | \$ 116,178 | \$ 170,019 |
| Accounts receivable | 85,427 | 72,953 |
| Inventory | 15,963 | 9,643 |
| Prepaid expenses and other current assets | 6,107 | 3,105 |
| Property and equipment, net | 13,145 | 11,854 |
| Operating lease assets | 8,873 | 9,047 |
| Intangible asset, net | 386,289 | 29,503 |
| Restricted cash | 2,645 | — |
| Other noncurrent assets | 166 | 178 |
| Total assets | \$ 634,793 | \$ 306,302 |
| Accounts payable and accrued expenses | 24,953 | 39,727 |
| Accrued rebates, returns and discounts | 171,886 | 157,549 |
| Term notes payable | 192,570 | 11,500 |
| Convertible senior notes | 94,383 | — |
| Operating lease liabilities | 9,938 | 10,094 |
| Stockholders' equity | 141,063 | 87,432 |
| Total liabilities and stockholders' equity | \$ 634,793 | \$ 306,302 |

Collegium Pharmaceutical, Inc.

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

| | Three months ended March 31, | |
|--|-------------------------------------|-------------|
| | 2020 | 2019 |
| Product revenues, net | \$ 76,511 | \$ 74,516 |
| Cost of product revenues | | |
| Cost of product revenues (excluding intangible asset amortization) | 27,229 | 45,476 |
| Intangible asset amortization | 10,295 | 3,688 |
| Total cost of products revenues | 37,524 | 49,164 |
| Gross profit | 38,987 | 25,352 |
| Operating expenses | | |
| Research and development | 2,666 | 2,992 |
| Selling, general and administrative | 31,260 | 32,352 |
| Total operating expenses | 33,926 | 35,344 |
| Income (loss) from operations | 5,061 | (9,992) |
| Interest expense | (4,823) | (234) |
| Interest income | 212 | 526 |
| Net income (loss) | \$ 450 | \$ (9,700) |
| Earnings (loss) per share — basic | \$ 0.01 | \$ (0.29) |
| Weighted-average shares — basic | 34,100,688 | 33,331,917 |
| Earnings (loss) per share — diluted | \$ 0.01 | \$ (0.29) |
| Weighted-average shares — diluted | 35,069,693 | 33,331,917 |

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP to Non-GAAP Financial Information

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

| | Three months ended | |
|---|---------------------------|-------------|
| | March 31, | |
| | 2020 | 2019 |
| GAAP net income (loss) | \$ 450 | \$ (9,700) |
| Non-GAAP adjustments: | | |
| Stock-based compensation expense ⁽¹⁾ | 4,951 | 4,263 |
| Intangible asset amortization ⁽²⁾ | 10,295 | 3,688 |
| Non-cash interest expense ⁽³⁾ | 1,336 | — |
| Nucynta royalty adjustment ⁽⁴⁾ | 14,216 | — |
| Total non-GAAP adjustments | \$ 30,798 | \$ 7,951 |
| Non-GAAP adjusted income (loss) | \$ 31,248 | \$ (1,749) |

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|----------------------|-----------------------|----------------------|-----------------------|
| | 2019 | 2019 | 2019 | 2019 |
| GAAP net loss | \$ (9,700) | \$ (4,712) | \$ (6,109) | \$ (2,201) |
| Non-GAAP adjustments: | | | | |
| Stock-based compensation expense ⁽¹⁾ | 4,263 | 4,162 | 4,137 | 3,966 |
| Intangible asset amortization ⁽²⁾ | 3,688 | 3,688 | 3,688 | 3,688 |
| Total non-GAAP adjustments | \$ 7,951 | \$ 7,850 | \$ 7,825 | \$ 7,654 |
| Non-GAAP adjusted income (loss) | \$ (1,749) | \$ 3,138 | \$ 1,716 | \$ 5,453 |

(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 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 Asserzio.