
**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, 2021

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
(IRS 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))

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

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 2.02 Results of Operations and Financial Condition.

On August 5, 2021, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended June 30, 2021. 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, 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.

Collegium Pharmaceutical, Inc.

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

Dated: August 5, 2021



Collegium Reports Strong Q2 Results with Cash Balance Growing to Over \$200 Million

– Xtampza® ER Market Share Grew to 31.5% of the Oxycodone Extended-Release Market in June 2021 –

– Net Income of \$72.8 Million and Adjusted EBITDA of \$40.1 Million –

– Full-Year 2021 Product Revenue Guidance Updated –

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

STOUGHTON, Mass., August 5, 2021 -- 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, 2021 and provided a corporate update.

“Collegium made meaningful progress against our corporate objectives in the second quarter, delivering strong financial results, driven by the underlying strength of our differentiated pain portfolio,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “The organization is in a phase of growth and value creation, and we are committed to delivering on our mission of being the leader in responsible pain management, while executing against our strategic priorities for the remainder of 2021.”

“In the second quarter, we generated significant cash flows and continued to leverage our cost structure,” said Colleen Tupper, Chief Financial Officer of Collegium. “Today, based on the ongoing impact of COVID-19 and portfolio gross-to-net dynamics, we are adjusting our revenue guidance for Xtampza ER and the Nucynta Franchise. Collegium remains in a strong financial position, and we are focused on investing in the long-term growth of our business and creating value for shareholders.”

Recent Business Highlights

- Colleen Tupper was appointed Executive Vice President and Chief Financial Officer, effective May 24, 2021.
- Xtampza ER was the fastest growing Branded ER product with prescriptions growing 6.9% over the first quarter of 2021 and 21.7% over the second quarter of 2020. Xtampza ER market share grew to 31.5% of the oxycodone extended-release market in June of 2021, up from 30.6% in March 2021.
- Nucynta® Franchise prescriptions grew 0.5% over the first quarter of 2021. Nucynta ER Branded ER market share was stable compared to the first quarter of 2021.
- The Company sponsored a publication titled, “Nonmedical Use of Xtampza ER and Other Oxycodone Medications in Adults Evaluated for Substance Abuse Treatment: Real-world Data from the Addiction Severity Index – Multimedia Version (ASI-MV®),” published in the peer-reviewed medical journal, *Journal of Pain Research*.

Financial Guidance for 2021

The Company updates its full-year 2021 financial guidance:

	<u>Prior</u>	<u>Updated</u>
Xtampza ER Revenues	\$155.0 to \$165.0 million	\$140.0 to \$150.0 million
Nucynta Franchise Revenues	\$185.0 to \$195.0 million	\$195.0 to \$205.0 million
Total Operating Expenses (Including Stock-Based Compensation)	\$125.0 to \$135.0 million	Reaffirmed
Adjusted EBITDA (Excluding Stock-Based Compensation)	\$170.0 to \$180.0 million	Reaffirmed

Collegium is not providing forward-looking guidance for its full-year 2021 U.S. GAAP net income (loss) or a quantitative reconciliation of forward-looking adjusted EBITDA. Please see “Non-GAAP Financial Measures” below for additional information.

Financial Results for Quarter Ended June 30, 2021

- Xtampza ER net product revenues were \$33.0 million for the quarter ended June 30, 2021 (the “2021 Quarter”), compared to \$33.6 million for the quarter ended June 30, 2020 (the “2020 Quarter”).
- Nucynta franchise net product revenues were \$49.9 million for the 2021 Quarter, compared to \$44.5 million for the 2020 quarter.
- Operating expenses, including stock-based compensation expense, were \$33.8 million for the 2021 Quarter, compared to \$31.8 million for the 2020 quarter. Operating expenses, excluding stock-based compensation, were \$27.3 million for the 2021 Quarter, compared to \$26.2 million for the 2020 Quarter, demonstrating the Company’s continued commitment to leveraging its existing cost structure.
- Net income for the 2021 Quarter was \$72.8 million, or \$2.06 earnings per share (basic) and \$1.79 earnings per share (diluted), compared to net income of \$8.1 million, or \$0.23 earnings per share (basic and diluted), for the 2020 quarter. Net income included stock-based compensation expense of \$6.5 million and \$5.6 million for the 2021 Quarter and the 2020 Quarter, respectively. Net income for the 2021 Quarter also includes a one-time non-cash adjustment of \$62.6 million, or \$1.77 per share (basic) and \$1.52 per share (diluted), due to the Company’s release of its tax valuation allowance on the majority of net operating losses and other deferred tax assets.
- Adjusted EBITDA for the 2021 Quarter was \$40.1 million, compared to \$39.1 million for the 2020 Quarter.

Conference Call Information

The Company will host a conference call and live audio webcast on Thursday, August 5, 2021, 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 Pharmaceutical Q2 2021 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 certain non-GAAP financial measures such as adjusted EBITDA and operating expenses, excluding stock-based compensation. We use these non-GAAP financial measures to understand, manage and evaluate our business as we believe they provide additional information on the performance of our business. We believe that the presentation of these non-GAAP financial measures, taken in conjunction with our results under GAAP, provide analysts, investors, lenders and other third parties insight into our view and assessment of our ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing our performance and results from period to period. We report these non-GAAP financial measures to portray the results of our operations prior to considering certain income statement elements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, and stock-based compensation. Adjusted EBITDA,

as used by us, may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income, which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude stock-based compensation expense from adjusted EBITDA although (a) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect the benefit from or provision for income taxes or the cash requirements to pay taxes; and
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments.

The Company has not provided a reconciliation of its full-year 2021 guidance for non-GAAP adjusted EBITDA 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, including, but not limited to, stock-based compensation expense. These items are uncertain and depend on various factors that could have a material impact on GAAP net income for the guidance period.

Operating expenses, excluding stock-based compensation is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense.

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, 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 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.; 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 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>2021</u>	<u>December 31,</u> <u>2020</u>
Cash and cash equivalents	\$ 202,771	174,116
Accounts receivable, net	90,098	83,320
Inventory	19,595	15,614
Prepaid expenses and other current assets	6,068	4,838
Property and equipment, net	19,555	18,988
Operating lease assets	8,023	8,391
Intangible asset, net	302,314	335,904
Restricted cash	2,547	2,547
Deferred tax assets	62,649	—
Other noncurrent assets	115	123
Total assets	\$ 713,735	\$ 643,841
Accounts payable and accrued expenses	34,929	34,672
Accrued rebates, returns and discounts	143,224	156,554
Term notes payable	133,863	157,514
Convertible senior notes	139,511	99,575
Operating lease liabilities	9,142	9,495
Shareholders' equity	253,066	186,031
Total liabilities and stockholders' equity	\$ 713,735	\$ 643,841

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,	
	2021	2020	2021	2020
Product revenues, net	\$ 82,942	\$ 78,058	\$ 170,663	\$ 154,569
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	15,908	12,899	31,236	40,128
Intangible asset amortization	16,795	16,795	33,590	27,090
Total cost of products revenues	32,703	29,694	64,826	67,218
Gross profit	50,239	48,364	105,837	87,351
Operating expenses				
Research and development	3,462	2,493	6,392	5,159
Selling, general and administrative	30,368	29,322	61,844	60,582
Total operating expenses	33,830	31,815	68,236	65,741
Income from operations	16,409	16,549	37,601	21,610
Interest expense	(5,421)	(8,259)	(11,142)	(13,082)
Interest income	3	14	6	226
Income before income taxes	10,991	8,304	26,465	8,754
(Benefit from) Provision for income taxes	(61,852)	246	(62,040)	246
Net income	\$ 72,843	\$ 8,058	\$ 88,505	\$ 8,508
Earnings per share — basic	\$ 2.06	\$ 0.23	\$ 2.52	\$ 0.25
Weighted-average shares — basic	35,302,608	34,395,266	35,128,144	34,247,977
Earnings per share — diluted	\$ 1.79	\$ 0.23	\$ 2.20	\$ 0.24
Weighted-average shares — diluted	41,286,853	35,091,906	41,251,749	35,089,740

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Net Income to Adjusted EBITDA

(in thousands)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
GAAP net income	\$ 72,843	\$ 8,058	\$ 88,505	\$ 8,508
Adjustments:				
Interest expense	5,421	8,259	11,142	13,082
Interest income	(3)	(14)	(6)	(226)
(Benefit from) provision for income taxes	(61,852)	246	(62,040)	246
Depreciation	425	196	864	394
Amortization	16,795	16,795	33,590	27,090
Stock-based compensation expense	6,516	5,584	13,395	10,535
Total adjustments	\$ (32,698)	\$ 31,066	\$ (3,055)	\$ 51,121
Adjusted EBITDA	\$ 40,145	\$ 39,124	\$ 85,450	\$ 59,629

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Operating Expenses to Operating Expenses, Excluding Stock-Based Compensation
(in thousands)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
GAAP Operating expenses	\$ 33,830	31,815	68,236	65,741
Stock-based compensation	6,516	5,584	13,395	10,535
Operating expenses, excluding stock-based compensation	<u>\$ 27,314</u>	<u>\$ 26,231</u>	<u>\$ 54,841</u>	<u>\$ 55,206</u>
