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): November 5, 2020

COLLEGIUM PHARMACEUTICAL, INC.

(Exact name of registrant as specified in its charter)

Virginia	**001-37372**	**03-0416362**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 November 5, 2020, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended September 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 November 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: November 5, 2020

Collegium Reports Net Income of $11.3 Million in the Third Quarter of 2020

– Strengthened Formulary Access for Xtampza® ER, Including Exclusive National Medicare Part D Win –

– Generated $34.2 Million in Cash Flow from Operations –

– Adjusted EBITDA of $41.8 Million –

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

STOUGHTON, Mass., November 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 quarter ended September 30, 2020 and provided a corporate update.

"In the third quarter, Collegium reported record net income, generated meaningful cash flow from operations and paid down debt," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "In the face of COVID-19, 2020 will be a financially transformative year for Collegium. Looking ahead to 2021, we believe the foundation is in place for the next phase of growth for Xtampza ER and stable profit contribution from the Nucynta franchise."

Recent Business Highlights

- Achieved exclusive formulary positions for Xtampza ER with a major national Medicare Part D plan and several regional commercial plans, as well as parity formulary positions for select regional commercial plans, effective January 1, 2021. With these new exclusive and parity formulary positions, Xtampza ER will be the exclusive branded ER oxycodone for more than 92 million lives and will be in a parity position for approximately 22 million lives.

- Reached a settlement with Teva Pharmaceutical USA, Inc. resolving patent litigation brought in response to Teva's Abbreviated New Drug Application, seeking approval to market a generic version of Xtampza ER prior to the expiration of Collegium's applicable patents. Collegium will grant Teva a license to market its generic version of Xtampza ER in the United States beginning on or after September 2, 2033 (subject to U.S. FDA approval, and customary exceptions).

- Strengthened Board of Directors with the appointment of Dr. Rita Balice-Gordon, effective September 24, 2020.

- Sponsored a publication titled, "Postmarketing Analysis of Misuse, Abuse and Diversion of Xtampza ER," published in the peer-reviewed medical journal, Pain Medicine. The publication presents real-world evidence related to abuse, misuse and diversion of Xtampza ER assessed using Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) system data sources.

Financial Results for Quarter Ended September 30, 2020

- Xtampza ER net product revenues were $32.1 million for the quarter ended September 30, 2020 (the "2020 Quarter"), compared to $26.5 million for the quarter ended September 30, 2019 (the "2019 Quarter") and $33.6 million for the quarter ended June 30, 2020, representing an increase of 21% and decrease of 4%, respectively.

- Nucynta franchise net product revenues were $47.1 million in the 2020 Quarter, compared to $46.5 million for the 2019 Quarter and $44.5 million for the quarter ended June 30, 2020, representing an increase of 1% and 6%, respectively.

- Operating expenses were $28.6 million for the 2020 Quarter, compared to $32.6 million for the 2019 Quarter, representing a decrease of 12%.

- Net income for the 2020 Quarter was $11.3 million, or $0.33 per share (basic) and $0.32 per share (diluted), compared to net loss of $6.1 million, or $0.18 loss per share (basic and diluted), for the 2019 Quarter.

- Non-GAAP adjusted income for the 2020 Quarter was $36.1 million, compared to non-GAAP adjusted income of $1.7 million for the 2019 Quarter.

- Adjusted EBITDA for the 2020 Quarter was $41.8 million, compared to adjusted EBITDA of $1.6 million for the 2019 Quarter.

- Cash flow from operations was $34.2 million in the 2020 Quarter, and $71.4 million for the nine months ended September 30, 2020.

Conference Call Information

The Company will host a conference call and live audio webcast on November 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 Q3 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 and adjusted EBITDA. We use these non-GAAP financial measures to understand, manage and evaluate the Company as we believe they represent the performance of our core business. Because these non-GAAP financial measures are important internal measures for the Company, we believe that the presentation of these non-GAAP financial measures provides analysts, investors, lenders and other third parties insight into management's view and assessment of the Company's 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 reconciliation, provide 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 these non-GAAP financial measures to portray the results of our major 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.

Non-GAAP adjusted income 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, certain royalty costs recognized in connection with the Nucynta Commercialization Agreement and the provision for income taxes. Non-GAAP adjusted income as used by us may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

Adjusted EBITDA represents GAAP net income (loss) adjusted to exclude interest expense, interest income, income tax expense, 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 (loss), 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 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 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.; 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:
Alex Dasalla
adasalla@collegiumpharma.com

Collegium Pharmaceutical, Inc.

Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 165,423	170,019
Accounts receivable	76,466	72,953
Inventory	17,146	9,643
Prepaid expenses and other current assets	3,097	3,105
Property and equipment, net	17,746	11,854
Operating lease assets	8,572	9,047
Intangible assets, net	352,699	29,503
Restricted cash	2,547	—
Other long-term assets	147	178
Total assets	$ 643,843	$ 306,302
Accounts payable and accrued expenses	24,201	39,727
Accrued rebates, returns and discounts	170,246	157,549
Term notes payable	169,248	11,500
Convertible senior notes	97,795	—
Operating lease liabilities	9,667	10,094
Shareholders' equity	172,686	87,432
Total liabilities and stockholders' equity	$ 643,843	$ 306,302

Collegium Pharmaceutical, Inc.

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Product revenues, net	$ 79,176	$ 72,942	$ 233,745	$ 222,498
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	14,188	43,066	54,316	133,508
Intangible asset amortization	16,795	3,688	43,885	11,064
Total cost of products revenues	30,983	46,754	98,201	144,572
Gross profit	48,193	26,188	135,544	77,926
Operating expenses				
Research and development	2,141	2,491	7,300	7,942
Selling, general and administrative	26,426	30,072	87,008	91,359
Total operating expenses	28,567	32,563	94,308	99,301
Income (loss) from operations	19,626	(6,375)	41,236	(21,375)
Interest expense	(8,063)	(228)	(21,145)	(698)
Interest income	3	494	229	1,552
Income (loss) before income taxes	11,566	(6,109)	20,320	(20,521)
Provision for income taxes	280	—	526	—
Net income (loss)	$ 11,286	$ (6,109)	$ 19,794	$ (20,521)
Earnings (loss) per share — basic	$ 0.33	$ (0.18)	$ 0.58	$ (0.62)
Weighted-average shares — basic	34,540,126	33,481,923	34,346,071	33,360,272
Earnings (loss) per share — diluted	$ 0.32	$ (0.18)	$ 0.56	$ (0.62)
Weighted-average shares — diluted	35,069,188	33,481,923	35,054,777	33,360,272

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
GAAP net income (loss)	$ 11,286	$ (6,109)	$ 19,794	$ (20,521)
Non-GAAP adjustments:				
Stock-based compensation expense(1)	5,165	4,137	15,700	12,562
Intangible asset amortization(2)	16,795	3,688	43,885	11,064
Non-cash interest expense(3)	2,567	—	6,427	—
Nucynta royalty adjustment (4)	—	—	14,216	—
Provision for income taxes (5)	280	—	526	—
Total non-GAAP adjustments	$ 24,807	$ 7,825	$ 80,754	$ 23,626
Non-GAAP adjusted income (loss)	$ 36,093	$ 1,716	$ 100,548	$ 3,105

(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.

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Net Income (Loss) to Adjusted EBITDA
(in thousands, except per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
GAAP net income (loss)	$ 11,286	$ (6,109)	$ 19,794	$ (20,521)
Adjustments:				
Interest expense	8,063	228	21,145	698
Interest income	(3)	(494)	(229)	(1,552)
Provision for income taxes	280	-	526	-
Depreciation	195	180	589	535
Amortization	16,795	3,688	43,885	11,064
Stock-based compensation expense	5,165	4,137	15,700	12,562
Total adjustments	$ 30,495	$ 7,739	$ 81,616	$ 23,307
Adjusted EBITDA	$ 41,781	$ 1,630	$ 101,410	$ 2,786