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): February 6, 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 \Box

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 7.01 Regulation FD Disclosure

On February 6, 2020, Collegium Pharmaceutical, Inc. (the "Company") issued a press release announcing that it has entered into a definitive agreement to acquire the U.S. rights to the Nucynta franchise of pharmaceutical products from Assertio Therapeutics, Inc. ("Assertio"). In connection with this announcement, the Company is making available on its website a copy of a presentation which provides an overview of the transaction between the Company and Assertio. A copy of the press release and the presentation are attached hereto as Exhibits 99.1 and 99.2, respectively.

In accordance with general instruction B.2 to Form 8-K, the information in this Item 7.01, including the press release and presentation incorporated by reference herein, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any other filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
<u>99.1</u>	<u>Press Release, dated February 6, 2020.</u>
<u>99.2</u>	Investor Presentation, dated February 6, 2020.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within 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: February 6, 2020



Collegium to Acquire U.S. Rights to Nucynta Franchise

- Financially Transformative Acquisition -

- Expected to Significantly Grow Net Income, EBITDA and Operating Cash Flows -

- Structure of the Financing Allows for Rapid De-Leveraging -

- Provides Financial Flexibility to Pursue Future Business Development Transactions -

STOUGHTON, Mass., Feb. 6, 2020 -- <u>Collegium Pharmaceutical, Inc.</u> (Nasdaq: COLL), a specialty pharmaceutical company committed to being the leader in responsible pain management, today announced that it has entered into a definitive agreement to acquire the U.S. rights to the Nucynta Franchise from Assertio Therapeutics, Inc. ("Assertio") for \$375.0 million in cash.

"Acquiring the full U.S. rights to the Nucynta Franchise is financially transformative for Collegium," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "We expect the acquisition to improve annual EBITDA and operating cash flows by more than \$100 million. The transaction is supported by a financing structure that allows for rapid de-leveraging and enables us to pursue future business development transactions."

Transaction Details

- Collegium will make a cash payment to Assertio of \$375.0 million, less royalties paid to Assertio in 2020, and subject to certain other adjustments. Collegium will assume the U.S. license for the Nucynta Franchise, and will no longer be required to pay royalties to Assertio.
- Collegium has secured debt financing commitments of \$325.0 million that, together with cash on hand, will be used to fund the purchase price payable to Assertio.
- Collegium will continue to pay Grunenthal GmbH a flat 14% royalty on net sales of the Nucynta Franchise, but will no longer be required to pay a supplemental royalty on sales greater than \$180.0 million.
- The transaction is expected to be immediately accretive and to significantly increase Collegium's profitability and operating cash flows.
- The deal is expected to close on February 14, 2020, subject to satisfaction of customary closing conditions.

The Nucynta Franchise

- The Nucynta Franchise, which includes both an extended-release and an immediate release formulation of tapentadol, is supported by patents with expiries in mid-June 2025, with the potential for a six-month pediatric extension.
- Importantly, Collegium assumes no liability, including litigation-related liability, related to the manufacture, sale or promotion of the Nucynta Franchise prior to Collegium's licensing of the U.S. commercialization rights on January 9, 2018.

Financial Guidance for 2020

Collegium reiterates its full-year 2020 financial guidance, initially provided on January 7, 2020:

- · Xtampza ER revenues are expected in the range of \$150.0 million to \$160.0 million.
- Nucynta Franchise revenues are expected in the range of \$170.0 million to \$180.0 million.
- Total operating expenses are expected in the range of \$130.0 million to \$140.0 million.

Advisors

Jefferies LLC acted as financial advisor to Collegium on the transaction, and Pepper Hamilton LLP served as legal counsel.

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 <u>www.collegiumpharma.com</u>.

About Xtampza ER

Xtampza[®] ER is Collegium's first product utilizing the DETERx technology platform. Xtampza ER is an abuse-deterrent, extended-release, oral formulation of oxycodone approved by the FDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

About Nucynta ER

Nucynta[®] ER is an extended-release formulation of tapentadol. Tapentadol is a centrally acting synthetic analgesic. Nucynta ER is approved by the FDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Nucynta ER is also approved by the FDA for neuropathic pain associated with diabetic peripheral neuropathy severe enough to require daily, around-the-clock, long-term options are inadequate.

About Nucynta

Nucynta[®] is an immediate release formulation of tapentadol indicated for the management of acute pain severe enough to require an opioid analgesic. Tapentadol is a centrally acting synthetic analgesic.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we have included information about EBITDA. We internally 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, 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 – commercializing innovative, differentiated products for people suffering from pain – 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. The Non-GAAP financial measure is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) before interest expense, interest income, income tax expense, depreciation expense and amortization expense. 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.

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 our expectations related to the consummation of the acquisition of the Nucynta assets and the potential impact 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and in other reports which we file 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 <u>adasalla@collegiumpharma.com</u>

Reconciliation of GAAP to Non-GAAP Financial Information (in thousands) (unaudited)

	Nine Months Ended September 30, 2019		Illustrative Pro Forma Annualized (1) Twelve Months Ended December 31, 2019	
GAAP net loss	\$	(20,521)	\$	(27,361)
EBITDA adjustments:		C00		021
Interest expense Interest income		698		931
Depreciation expense		(1,552) 535		(2,069) 713
Amortization expense				
Total EBITDA adjustments	¢	11,064	¢	14,752
Total EDITDA aujustments	\$	10,745	\$	14,327
EBITDA	<u>\$</u>	(9,776)	\$	(13,034)
Illustrative Pro Forma Adjustments				
Nucynta royalties due to Assertio (2)		94,163		118,842
Nucynta royalties due to Grunenthal (3)		_		6,958
Total Illustrative Pro Forma Adjustments	\$	94,163	\$	125,800
Illustrative Pro Forma EBITDA	\$	84,387	\$	112,766
Change in EBITDA	\$	94,163	\$	125,800

(1) Represents illustrative pro forma annualized GAAP net loss, interest expense, interest income, depreciation expense, and amortization expense based on annualizing the amounts disclosed for the nine months ended September 30, 2019 in the Condensed Consolidated Financial Statements as filed on Form 10-Q for the period ending September 30, 2019.

(2) Represents calculated royalties due to Assertio under the Third Amendment to the Nucynta Commercialization Agreement, which are no longer required under the agreement to acquire the Nucynta Franchise. For the nine months ended September 30, 2019, the Company recognized product revenues, net from the Nucynta Products of \$144,866, which results in \$94,163 of calculated royalties due to Assertio (65% of net product revenues from the Nucynta Products). The Company's illustrative pro forma annualized product revenues, net from the Nucynta Products is \$193,155, which results in \$118,842 of calculated royalties due to Assertio (65% of net product revenues up to \$180,000, or \$117,000, plus 14% of net product revenues from \$180,000 to \$193,155, or \$1,842, for total calculated royalties due of \$118,842).

(3) Represents the change in calculated royalties due to Grunenthal under the agreement to acquire the Nucynta Franchise compared to the Third Amendment to the Nucynta Commercialization Agreement. The Company was previously required to pay a guaranteed \$34,000 royalty to Grunenthal if net product revenues from the Nucynta Products exceeded \$180,000. Under the agreement to acquire the Nucynta Franchise, such guarantee has been eliminated and is replaced with a flat royalty of 14% of net product revenues from the Nucynta Products. As such, the difference between 14% of illustrative pro forma annualized net product revenues of \$193,155, or \$27,042, and \$34,000 is \$6,958.



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. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results 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 our expectations related to the consummation of the acquisition of the Nucynta assets and the potential impact 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and in other reports which we file 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.



Nucynta Acquisition: Financially Transformative for Collegium

Expected to: Increase EBITDA by > \$100m / year



Please refer to the GAAP v. Non-GAAP reconciliation set forth in the Appendix to this presentation, which reflects the pro forma, illustrative impact of the transaction on EBITDA for 2019 (on an annualized basis), and a reconciliation of EBITDA to GAAP Net Income.



Nucynta Acquisition Transaction Details

Terms	 Cash payment of \$375.0m, subject to certain conditions, including: Adjustments for inventory and royalties paid in 2020 Will assume U.S. license for Nucynta IP Will pay Grunenthal GmbH a flat 14% royalty on net sales Will no longer be required to pay a royalty to Assertio
Financing	 Purchase price funded with: \$325.0m of committed debt financing cash on hand Financing structured to limit the impact of dilution Cash flow profile and financing terms expected to enable de-leveraging
Timing	 Unanimously approved by Collegium's Board of Directors Expected to close by February 14, 2020 Subject to customary closing conditions
4	

Prior Nucynta Deal vs. New Nucynta Deal

Prior Nucynta Deal

- Opportunistic Financial Transaction
 - Immediately Accretive
 - Accelerated Time to Profitability
 - Improved Cash Flows
- Broadened Product Portfolio
- Leveraged Current Infrastructure
- × Not Financially Transformative
- × Did Not Retain Majority of Economics

New Nucynta Deal

- Financially Transformative Deal is expected to:
 - Drive Profitability
 - Improve Gross Margin
 - Transform EBITDA and Cash Flows from Operations
- Expected to Enable De-Leveraging
- Expected to Provide Flexibility for Diversification



Nucynta Acquisition: Illustrative Financial Impact

Annualized Revenues for Nucynta Franchise	Illustrative Operating Cash Flow to Collegium ¹		
	Prior Deal	New Deal	
\$193.2m ²	\$40.4m ³	\$166.2m ³	

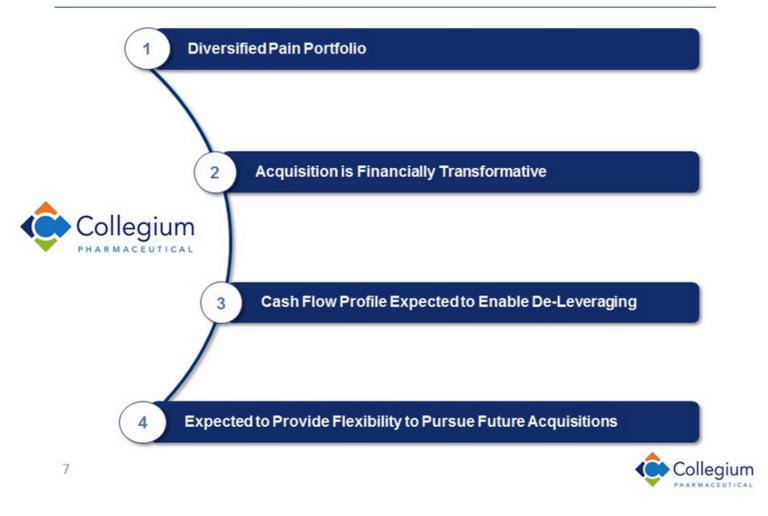
Note 1: Presented as an illustration of the impact of the new deal, had it been in effect as of January 1, 2019, and not meant to be indicative of what our historical or future results would have been or will be.

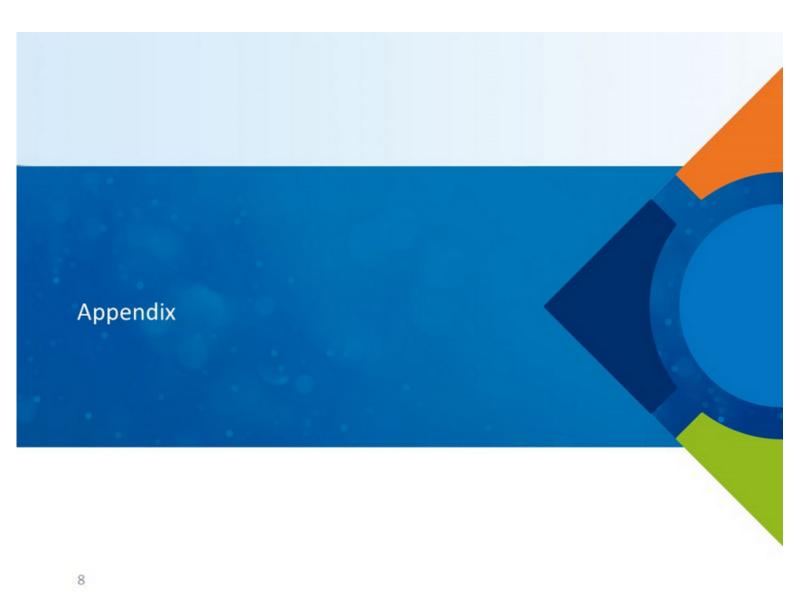
Note: 2: This figure represents the 2019 annualized product revenues, net of the Nucynta franchise, based on the amounts disclosed for the nine months ended September 30, 2019 in the Notes to our Condensed Consolidated Financial Statements as filed on Form 10-Q for the period ending September 30, 2019.

Note 3: Under the new deal, royalties are no longer required to be paid to Assertio. In addition, under the prior deal, if the annual net sales of the Nucynta franchise equal or exceed \$180.0m, Collegium was required to pay a guaranteed \$34.0m royalty to Grunenthal. Under the new deal, such guarantee has been eliminated and is replaced with a flat 14% royalty payable to Grunenthal.



Nucynta Acquisition Highlights





Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we have included information about EBITDA. We internally 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, 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 - commercializing innovative, differentiated products for people suffering from pain - 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. The Non-GAAP financial measure is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) before interest expense, interest income, income tax expense, depreciation expense and amortization expense. 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.



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