



Collegium to Acquire Ironshore Therapeutics, Expanding into Neurology

July 29, 2024

– Adds Commercial Product Jornay PM[®], Establishing Collegium's Presence in Neurology (ADHD) –

– H1'24 Jornay PM Prescriptions Grew 32% Year-over-Year –

– Transaction Expected to be Immediately Accretive to Adjusted EBITDA –

– Acquisition Funded by Collegium's Cash on Hand and New Five-Year Financing with Significantly Improved Terms –

– Collegium Estimates Q2'24 Pain Portfolio Net Revenue of \$145 Million, Up 7% Year-over-Year; Reaffirms 2024 Financial Guidance for the Current Business –

– Conference Call Scheduled for Today at 8:30 a.m. ET –

STOUGHTON, Mass. and GEORGE TOWN, Cayman Islands, July 29, 2024 (GLOBE NEWSWIRE) -- [Collegium Pharmaceutical, Inc.](#) (Nasdaq: COLL) and Ironshore Therapeutics Inc. today announced a definitive agreement pursuant to which Collegium will acquire Ironshore for \$525 million in cash with the potential for an additional \$25 million commercial milestone payment.

Ironshore is a privately held, pharmaceutical company that markets and distributes Jornay PM (methylphenidate HCl), a central nervous system (CNS) stimulant prescription medicine for the treatment of attention deficit hyperactivity disorder (ADHD) in people six years of age and older and the only stimulant medication that is dosed in the evening. The acquisition of Ironshore will represent a significant milestone in advancing Collegium's mission of building a leading, diversified specialty pharmaceutical company by expanding the Company's business beyond pain management and establishing a commercial presence in a new and growing market.

"The Ironshore acquisition is a unique opportunity to deliver a transaction that is immediately accretive to Collegium while meeting all of our strategic objectives through the addition of a growing commercial asset that diversifies our portfolio, has significant revenue potential and exclusivity into the 2030s," said Michael Heffernan, Chairman and Interim President and Chief Executive Officer of Collegium. "The addition of Jornay PM will establish a new presence for Collegium in ADHD, a large and growing market, where we can leverage our core commercial competencies and proven commercial execution capabilities to maximize the brand's potential. Our healthy balance sheet and strong financial position enabled us to secure attractive financing for the transaction with terms that reduce our cost of capital and enhance our flexibility in the management of our debt."

"We are pleased to announce this transaction with Collegium, which recognizes the value of Jornay PM and the success of Ironshore's talented team in the delivery of an important and differentiated treatment option for patients with ADHD and their caregivers," said Stephanie Read, Chief Executive Officer of Ironshore. "Our team has worked tirelessly to bring Jornay PM to the ADHD community and we are excited that Collegium recognizes Jornay PM's long-term potential and is committed to supporting its continued growth."

Transaction Rationale

- Strategically aligns with Collegium's mission of building a leading, diversified specialty pharmaceutical company by broadening the commercial portfolio beyond pain management and establishing a commercial presence in neurology via the large and growing ADHD market.
- Jornay PM is poised to become Collegium's leading growth driver. Net revenue for Jornay PM is expected to be in excess of \$100 million in 2024. In the first half of 2024, Jornay PM prescriptions grew 32% year-over-year. For the full-year 2023, the product generated approximately 490,000 prescriptions, a 58% increase compared to 2022. Jornay PM is a highly differentiated treatment for ADHD due to its evening dosing, smooth therapeutic effect and dose-dependent duration.
- Jornay PM is supported by 16 Orange Book-listed patents, with expiries in 2032.
- Further strengthens Collegium's financial position through an increased revenue base, expected immediate accretion to adjusted EBITDA and accelerated cash flow generation.

Additional Transaction Details

- Under the terms of the agreement, Collegium will acquire all the outstanding shares of Ironshore for \$525 million in cash at closing. Collegium will also pay Ironshore shareholders \$25 million in additional consideration if Jornay PM net revenue exceeds a defined threshold in 2025.
- The all-cash consideration will be funded by a combination of Collegium's existing cash on hand and a \$646 million secured financing from funds managed by Pharmakon Advisors, LP (Pharmakon). The new five-year term loan will replace the existing Collegium term loan from Pharmakon and reduce the interest rate by 300 basis points.
- At year-end 2024, Collegium expects net leverage to be less than two times based on estimated 2024 pro forma combined adjusted EBITDA.
- Collegium expects this transaction to be immediately accretive to adjusted EBITDA, excluding transaction costs.

Timing to Close

The transaction, which has been unanimously approved by the boards of directors of both companies, is expected to close in the third quarter of 2024, subject to customary closing conditions, including receipt of required regulatory approvals.

Advisors

Lazard is acting as the exclusive financial advisor to Collegium. Centerview Partners is acting as the exclusive financial advisor to Ironshore. Hogan Lovells is serving as M&A legal counsel to Collegium. Goodwin Procter LLP is serving as M&A legal counsel to Ironshore. Cleary Gottlieb Steen and

Hamilton LLP is serving as legal counsel to Ironshore shareholders.

Collegium Preliminary Second Quarter 2024 Financial Results

For the second quarter ended June 30, 2024, Collegium estimates net product revenues of \$145 million, up 7% year-over-year.

Final second quarter 2024 financial results will be announced after market close on Thursday, August 8, 2024.

Financial Guidance for 2024

The Company reaffirms its full-year 2024 guidance for Product Revenues, Net, Adjusted Operating Expenses and Adjusted EBITDA for its current business, not including the impact of the planned acquisition of Ironshore.

Product Revenues, Net	\$580.0 to \$595.0 million
Adjusted Operating Expenses (Excluding Stock-Based Compensation)	\$120.0 to \$125.0 million
Adjusted EBITDA (Excluding Stock-Based Compensation)	\$380.0 to \$395.0 million

Conference Call and Webcast

Collegium will host a conference call and live audio webcast to discuss the acquisition of Ironshore Therapeutics on Monday, July 29, 2024, at 8:30 a.m. ET. To access the conference call, please dial (877) 407-8037 (U.S.) or (201) 689-8037 (International) and reference the "Collegium Pharmaceutical Investor Conference 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 JORNAY PM®

JORNAY PM (methylphenidate HCl extended-release capsules) is a central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

- JORNAY PM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.
- Before prescribing JORNAY PM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout JORNAY PM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse and addiction.

See additional important safety information below.

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

JORNAY PM can cause serious adverse reactions and patients should be monitored for the following:

- *Risks to Patients with Serious Cardiac Disease:* Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.
- *Increased Blood Pressure and Heart Rate.*
- *Psychiatric Adverse Reactions:* Including exacerbation of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder, induction of a manic episode in patients with bipolar disorder, and new psychotic or manic symptoms. Prior to initiating treatment, screen patients for risk factors for psychiatric adverse reactions. If such symptoms occur, consider discontinuing JORNAY PM.
- *Priapism:* Patients should seek immediate medical attention.
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* Observe patients for digital changes during treatment.
- *Weight Loss and Long-Term Suppression of Growth in Pediatric Patients:* Monitor height and weight.
- *Increased Intraocular Pressure (IOP) and Glaucoma:* Patients at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist. Closely monitor patients with a history of abnormally increased IOP or open angle glaucoma.
- *Onset or Exacerbation of Motor and Verbal Tics, and Worsening of Tourette's Syndrome.*

ADVERSE REACTIONS

- The most common (≥5% and twice the rate of placebo) adverse reactions with methylphenidate are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- Additional adverse reactions (≥5% and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years are headache, psychomotor hyperactivity, and mood swings.

DRUG INTERACTIONS

- Antihypertensive drugs: Monitor blood pressure data. Adjust dosage of antihypertensive drug as needed.

To report SUSPECTED ADVERSE REACTIONS, contact Ironshore Pharmaceuticals Inc. at 1-877-938-4766 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please visit <https://ironshorepharma.com/jornay-pm-label> for additional important safety information and the Full Prescribing Information, including Boxed Warning, for JORNAY PM.

About Collegium Pharmaceutical, Inc.

Collegium is a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit the Company's website at www.collegiumpharma.com.

About Ironshore Therapeutics Inc.

Ironshore Therapeutics Inc. is a pharmaceutical company whose mission is to commercialize innovative, patient-focused treatment options to improve the lives of patients and caregivers.

Preliminary Second Quarter 2024 Financial Results

The preliminary, unaudited financial results included in this press release are based on information available as of July 29, 2024, and management's initial review of operations for the second quarter ended June 30, 2024. They remain subject to change based on management's ongoing review of the second quarter and are forward-looking statements. We assume no obligation to update these statements. The actual results remain subject to the completion of management's and our audit committee's reviews and our other financial closing procedures. During that process, we may identify items that would require us to make adjustments, which may be material, to the information presented in this press release. While we do not expect that our actual results for the second quarter ended June 30, 2024, will vary materially from the preliminary, unaudited financial results presented in this press release, there can be no assurance that these estimates will be realized. Actual results may be materially different and are affected by the risk factors and uncertainties identified in this press release and in our quarterly filings with the Securities and Exchange Commission (SEC).

These preliminary, unaudited results should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes thereto included in our Quarterly Report on Form 10-Q for the period ended March 31, 2024, which has been filed with the SEC. The preliminary, unaudited financial information presented herein should not be considered a substitute for the financial information to be filed with the SEC in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, once it becomes available.

Non-GAAP Financial Measures

We have included information about certain non-GAAP financial measures in this press release. 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 the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide analysts, investors, lenders, and other third parties with insights into how we evaluate normal operational activities, including our ability to generate cash from operations, on a comparable year-over-year basis and manage our budgeting and forecasting. In addition, certain non-GAAP financial measures, primarily Adjusted EBITDA, are used to measure performance when determining components of annual compensation for substantially all non-sales force employees, including senior management.

In this press release we discuss the following financial measures that are not calculated in accordance with GAAP.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. 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 or 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: (i) 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 (ii) 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;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
- we exclude impairment expenses from adjusted EBITDA and, although these are non-cash expenses, the asset(s) being impaired may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred;
- we exclude acquisition related expenses as the amount and/or frequency of these expenses are not part of our underlying business. Acquisition related expenses include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and

other consulting fees, incurred to complete the acquisition, employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, and miscellaneous other acquisition related expenses incurred;

- we exclude recognition of the step-up basis in inventory from acquisitions (i.e., the adjustment to record inventory from historic cost to fair value at acquisition) as the adjustment does not reflect the ongoing expense associated with sale of our products as part of our underlying business; and
- we exclude losses on extinguishments of debt as these expenses are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis.

Adjusted Operating Expenses

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations.

We have not provided a reconciliation of our full-year 2024 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonable efforts exception provided under Item 10(e)(1)(i)(B) of Regulation S-K, because we are 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, acquisition related expense and litigation settlements. These items are uncertain and depend on various factors that are outside of our control or cannot be reasonably predicted. While we are unable to address the probable significance of these items, they could have a material impact on GAAP net income and operating expenses for the guidance period. A reconciliation of adjusted EBITDA or adjusted operating expenses would imply a degree of precision and certainty as to these future items that does not exist and could be confusing to investors.

Collegium 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 related to the acquisition of Ironshore Therapeutics and the anticipated timing and benefits thereof, the anticipated financial impact of the acquisition of Ironshore Therapeutics, our expectations for Jornay PM revenues, to our full-year 2024 financial guidance, including projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. 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, including risks relating to, among others: risks related to our ability to complete the transaction on the proposed terms and schedule or at all; the failure (or delay) to receive the required regulatory approvals relating to the transaction; risks related to our ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of this announcement or the consummation of the proposed acquisition on the market price of our common stock and/or operating results; risks related to significant transaction costs or the acquisition of unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition; risks related to future opportunities and plans for Ironshore Therapeutics and Jornay PM, including uncertainty of the expected financial performance of such 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 maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of our products; the size of the markets for our products, 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; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement or other litigation that may be brought by or against us; 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 Annual Reports on Form 10-K and Quarterly Reports 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.

Ironshore Forward-Looking Statements

This press release contains forward-looking information, which reflects the company's current expectations regarding future events. Forward-looking information is based on a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond the company's control that could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking information. These forward-looking statements are made as of the date of this press release and, except as expressly required by applicable law, the company assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Collegium Contacts:

Investor Contact:

Christopher James, M.D.
Vice President, Investor Relations
ir@collegiumpharma.com

Media Contact:

Marissa Samuels
Vice President, Corporate Communications
communications@collegiumpharma.com

Ironshore Contacts:

Media Contact:

Audrey Gross
audrev.gross@ironshorepharma.com



Source: Collegium Pharmaceutical, Inc.