

**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 2, 2023

Collectar Biosciences, Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

1-36598
(Commission
File Number)

04-3321804
(IRS Employer
Identification No.)

100 Campus Drive, Florham Park, NJ, 07932
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (608) 441-8120

N/A
(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 \$0.00001 per share	CLRB	The Nasdaq Capital 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 November 2, 2023, we issued a press release announcing preliminary financial results for the three months ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits
Number

Title

99.1 [Press release dated November 2, 2023, entitled "Collectar to Release Top-line Data from WM Pivotal Trial During the JP Morgan Healthcare Conference the Week of January 8, 2024"](#)

104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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.

CELLECTAR BIOSCIENCES, INC.

Date: November 2, 2023

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer

Collectar to Release Top-line Data from WM Pivotal Trial During the JP Morgan Healthcare Conference the Week of January 8, 2024

Reports Preliminary Financial Results for Third Quarter 2023 and Provides a Corporate Update

Conference Call scheduled for today at 8:30 am Eastern Time

FLORHAM PARK, N.J., Nov. 2, 2023 -- Collectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of targeted drugs for the treatment of cancer, today announced that top-line data from the pivotal trial in Waldenstrom's macroglobulinemia (WM) will be released during the JP Morgan Healthcare conference the week of January 8, 2024.

Third Quarter and Recent Corporate Highlights

- Closed a securities purchase agreement with certain institutional investors for a private placement financing that, based on potential milestone payments, is expected to result in gross proceeds of up to \$102.9 million, including an initial funding of \$24.5 million. The PIPE was priced at the company's common stock closing price on September 1, 2023, of \$1.82 per share. The financing was led by Rosalind Advisors with participation from AIGH Capital, ADAR1, Second Line, Nantahala Capital, AuGC and other new and existing institutional investors.
- Received European Medicines Agency Priority Medicines (PRIME) Designation for iopofosine I 131 for Waldenstrom's macroglobulinemia in patients who have received two or more prior treatment regimens. The PRIME designation was awarded based upon data from a pre-planned interim assessment in the pivotal study and six patients from the Phase 2a. PRIME designation is accorded to new therapies that demonstrate the potential to significantly address an unmet medical need in clinical trials. Also, it allows companies to optimize development plans and accelerate evaluation of medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options.
- Continued engagement with the U.S. Food and Drug Administration (FDA) providing additional regulatory clarity on the pivotal clinical trial and planned new drug application (NDA) submission in 2024. This includes direct feedback on key sections of the NDA and input around the design of a confirmatory study to support the accelerated approval strategy.
- Expanded the company's global intellectual property portfolio with the addition of four patent grants. The patents, which are valid across key global regions of Europe, Australia, and Canada, cover iopofosine I 131 and the company's proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform.

- Enhanced the company's commercial leadership team with the appointment of two new seasoned executives, William Yoon as vice president, medical affairs and Aaditya Nanduri as vice president, business strategy and analytics.

"We continue to collect and evaluate patient data from our pivotal trial and expect to announce top-line data the week of January 8, 2024. We view this data announcement as a potentially transformational event for Collectar and as such merits optimal market and industry awareness, which the JP Morgan conference provides. As we prepare to announce trial data, we continue to work with the FDA and progress the NDA submission while advancing our commercialization readiness," said James Caruso, president and CEO of Collectar. "With the recent financing providing up to \$102.9 million in funding, we believe the company is well positioned for success with a clearly differentiated lead asset poised to establish a new standard of care for patients with relapsed or refractory WM."

Preliminary Third Quarter 2023 Financial Highlights

- **Cash and Cash Equivalents:** As of September 30, 2023, the company had cash and cash equivalents of \$19.0 million, compared to \$19.9 million as of December 31, 2022. During the third quarter, the company entered into a securities purchase agreement with certain institutional investors for a private placement financing that is expected to result in gross proceeds of up to \$102.9 million, based upon achievement of certain milestones. Current cash includes an initial funding of \$22.2 million from the transaction, net of commissions and fees. The company believes its cash on hand is adequate to fund budgeted operations into the second quarter of 2024.
- **Research and Development Expense:** R&D expense for the three months ended September 30, 2023 was approximately \$7.3 million, compared to approximately \$5.4 million for the three months ended September 30, 2022. The overall increase in research and development expense was primarily a result of an increase in WM pivotal trial patient enrollment and expansion of the central nervous system lymphoma cohort of the company's Phase 2a basket trial in blood-borne malignancies as well as initiating its pediatric study in high-grade gliomas.
- **General and Administrative Expense:** G&A expense for the three months ended September 30, 2023, was \$2.1 million, compared to \$2.4 million for the same period in 2022. The overall decrease in G&A costs was primarily driven by reduced professional fees.

Conference Call & Webcast Details

Collectar management will host a conference call for investors today, November 2, 2023, beginning at 8:30 am Eastern Time to discuss these results and answer questions. Stockholders and other interested parties may participate in the conference call by dialing 1-888-886-7786 (in the U.S.) or 1-416-764-8658 (outside the U.S.). The call will be available via webcast by [clicking HERE](#) or on the [Events](#) page of the company's website.

About Collectar Biosciences, Inc.

Collectar Biosciences is a late-stage clinical biopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer, independently and through research and development collaborations. The company's core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop the next-generation of cancer cell-targeting treatments, delivering improved efficacy and better safety as a result of fewer off-target effects.

The company's product pipeline includes lead asset iopofosine I 131, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit www.collectar.com and www.wmclinicaltrial.com or join the conversation by liking and following us on the company's social media channels: Twitter, LinkedIn, and Facebook.

Forward-Looking Statement Disclaimer

This news release contains forward-looking statements. You can identify these statements by our use of words such as "may," "expect," "believe," "anticipate," "intend," "could," "estimate," "continue," "plans," or their negatives or cognates. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes including our expectations regarding the WM CLOVER-WaM pivotal trial. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, uncertainties related to the disruptions at our sole source supplier of iopofosine, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for iopofosine, the volatile market for priority review vouchers, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2022, and our Form 10-Q for the quarter ended June 30, 2023. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

Contacts

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