
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): June 12, 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 7.01. Regulation FD Disclosure.

On June 12, 2023, the Company issued a press release providing a research and development program summary. A copy of the press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

Item 8.01. Other Events.

On June 12, 2023, the Company issued a press release that included updated guidance related to its Waldenstrom’s macroglobulinemia (WM) CLOVER-WaM pivotal trial. The company now expects to release top-line data from the WM CLOVER-WaM trial in the second half of 2023.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Number	Title
99.1	Press release, dated June 12, 2023, entitled, “Celectar Provides a Research and Development Program Summary”
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: June 13, 2023

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer

Collectar Provides a Research and Development Program Summary

Waldenstrom's macroglobulinemia pivotal trial topline data now expected second half of 2023; pediatric high grade glioma trial to initiate in Q3

Phospholipid drug conjugate platform validation with alpha emitting radioisotopes, small molecules, peptides and oligos

FLORHAM PARK, N.J., June 12, 2023 -- Collectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted treatments for cancer, today provided an update for its iopofosine I 131 clinical program and guidance related to its Waldenstrom's macroglobulinemia (WM) CLOVER-WaM pivotal trial, as well as preclinical advancements to its proprietary phospholipid ether drug conjugate platform.

WM CLOVER-WaM pivotal trial

The company now expects to release top-line data from the WM CLOVER-WaM trial in the second half of 2023 and assuming NDA approval, remains on target for a 2024 product launch. Collectar experienced delays with trial start-up activities, such as site contracting and country regulatory responses, which slowed the initial pace of site initiations resulting in lower-than-expected patient enrollment. The company now has all 49 sites up and running and patient enrollment rates have accelerated. As has been previously reported, and in agreement with the FDA, WM CLOVER-WaM is a single arm, open label trial with a target enrollment of 50 patients.

"Although we are disappointed with the delay in the study's completion, our ongoing commercial preparations have compressed timelines and support a 2024 launch. Trial activations at high patient volume sites over recent quarters have increased the enrollment trend giving us confidence in our ability to complete the WM CLOVER-WaM study in the second half of 2023," said Dr. Andrei Shustov, Collectar's senior vice president, medical. "Iopofosine I 131 demonstrated a 100% overall response rate, an 83.3% major response rate and a 16.7% complete response rate in our Phase 2a study of six WM relapsed/refractory patients. In addition to these impressive response rates, iopofosine I 131's fixed, short-duration therapy removes the need for the indefinite or prolonged maintenance treatment that is currently required for other therapies."

Phase 1b study in pediatric high-grade gliomas

With the support of a \$2 million grant from the National Institute of Health's National Cancer Institute (NCI) the company plans to initiate a Phase 1b study in pediatric high-grade gliomas (pHGGs) in the third quarter of 2023. The study objective is to identify the recommended iopofosine I 131 Phase 2 dose in pHGG patients. The NCI grant was in part driven by the Phase 1a trial data demonstrating a near tripling of the progression free survival typically observed in relapsed/refractory patients.

Central nervous system lymphoma

Iopofosine I 131's ability to cross the blood-brain barrier and recently demonstrated activity in central nervous system lymphoma (CNSL) provides further rationale for treatment of WM patients with CNSL involvement, also known as Bing-Neel syndrome.

Based upon achieving a complete response in a CNSL patient treated as part of its Phase 2a trial, the company expanded the CNSL cohort to further evaluate iopofosine I 131 in this indication. Currently, there are no approved therapies available to CNSL patients.

Multiple myeloma

Iopofosine I 131 has been evaluated in over 125 multiple myeloma patients including triple class refractory, quad/penta refractory, high-risk and post-BCMA patients with response rates ranging from 40 to 62%. The company's recently published post BCMA response rate of 50% prompted expansion of this cohort in our ongoing Phase 2a trial.

The company's COO, Jarrod Longcor, will deliver an oral presentation of iopofosine I 131 in multiple myeloma at the Society of Nuclear Medicine and Molecular Imaging Annual Conference. The presentation is on June 26th (#P1243, *Using targeted radiotherapy in highly refractory multiple myeloma*).

Phospholipid ether cancer targeting platform

Development of the company's phospholipid ether cancer targeting platform continues to demonstrate its broad utility to provide targeted intracellular delivery of multiple cancer treatment modalities. Preclinical data recently presented at several conferences demonstrate the broad utility of the platform, including:

- multiple alpha-emitter radiotherapeutic programs targeting solid tumors;
- the activity of multiple cytotoxic small molecule payloads in triple negative breast cancer mouse models including eradication of the tumors with no subsequent regrowth;
- the successful delivery, uptake, and gene knockdown in a mouse model of pancreatic cancer with siRNA-phospholipid ether when given intravenously; and,
- the conjugation and use of peptides against intracellular targets where small molecules may not be effective.

James Caruso, president and CEO of Collectar said, "The company's priority remains the near-term completion of our WM pivotal study. Iopofosine I 131's Fast Track Designation allows for a six-month FDA review of our submission. In parallel, we continue to advance the clinical development of iopofosine I 131 for both adult and pediatric indications while efficiently executing on potentially value-creating research to best understand the wide-ranging capacity of our proprietary delivery platform."

About Collectar Biosciences, Inc.

Collectar Biosciences is focused on the discovery and development of drugs for the treatment of cancer. The company is developing proprietary drugs 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 PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's product pipeline includes iopofosine, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, open-label, pivotal expansion cohort in relapsed or refractory WM patients who have received at least two prior lines of therapy, including those who have failed or had a suboptimal response to Bruton tyrosine kinase inhibitors. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine for marketing approval. The company is also evaluating iopofosine in highly refractory multiple myeloma patients in its Phase 2 CLOVER-1 study and relapsed/refractory pediatric cancer patients with sarcomas or brain tumors in the Phase 1 CLOVER-2 study.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The Phase 1 study is being conducted internationally at seven leading pediatric cancer centers.

The company has established exclusivity on a broad U.S. and international intellectual property rights portfolio around its proprietary cancer targeting PLE technology platform, including iopofosine and its PDC programs.

In addition to the company's exclusivity to iopofosine and its phospholipid ethers conjugated to small molecules, peptides, and oligos, the company now has non-exclusive rights to the use of the phospholipid ether platform when conjugating with a chelator to bind select metal radioisotopes.

For more information, please visit www.cellectar.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 of the impact of the COVID-19 pandemic. 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. 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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