

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: June 11, 2015
(Date of earliest event reported)

CELLECTAR 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 Number)

3301 Agriculture Drive
Madison, WI 53716
(Address of principal executive offices)

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

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))
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ITEM 7.01 REGULATION FD DISCLOSURE

On June 11, 2015, we issued a press release announcing that after review of the company’s investigational new drug (IND) application the U.S. Food and Drug Administration (FDA) has determined that Collectar’s tumor margin illumination agent, CLR1502, will be evaluated as a combination product and assigned to the Center for Devices and Radiological Health. 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 June 11, 2015, entitled “Collectar Biosciences Announces CLR1502 Development Program to be Classified as Combination Product by U.S. Food and Drug Administration”

SIGNATURE

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.

Dated: June 11, 2015

CELLECTAR BIOSCIENCES, INC.

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Vice President and Chief Financial Officer

EXHIBIT INDEX

Number	Title
99.1	Press release dated June 11, 2015, entitled “Collectar Biosciences Announces CLR1502 Development Program to be Classified as Combination Product by U.S. Food and Drug Administration”



**Cellecstar Biosciences Announces CLR1502 Development Program to be
Classified as Combination Product by U.S. Food and Drug Administration**

*Cellecstar to Re-submit Investigational Application as Combination Product Prior to Initiating
Proof-of-Concept Trial of Tumor Margin Illumination Agent in Breast Cancer Surgery*

MADISON, Wis., June 11, 2015, – Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a clinical stage biopharmaceutical company developing innovative agents for the detection and treatment of cancer, announced today that, after review of the company's investigational new drug (IND) application, the U.S. Food and Drug Administration (FDA) has determined that Cellecstar's tumor margin illumination agent, CLR1502, will be evaluated as a combination product and assigned to the Center for Devices and Radiological Health (CDRH). As a result of this classification, the FDA has advised Cellecstar that it will need to submit a new investigational application for the combination product prior to initiating its planned proof-of-concept trial in breast cancer surgery.

"Our tumor illumination agent shares similar spectral qualities with indocyanine green (ICG), a fluorescent dye commonly used in medical diagnostics, and can therefore use several commercially available fluorescent imaging devices. Current labeling for such devices is limited to FDA approved applications such as cardiac, circulatory, hepatic and ophthalmic conditions," said Dr. Simon Pedder, president and chief executive officer of Cellecstar Biosciences. "Because of the groundbreaking nature of our overall technology and the potential for an agent like CLR1502 to dramatically expand the utility of such imaging devices, we appreciate the agency's perspective and current interest in evaluating CLR1502 in combination with a light source technology. As previously disclosed, in the course of our discussions FDA regarding the CLR1502 registration program, the FDA has stressed that a combination product designation is not binding, can be revised later in our development program, and that we are not necessarily precluded from filing a standalone NDA in the future."

About CLR1502

CLR1502 is a small-molecule, broad-spectrum, cancer-targeted, non-radioactive optical imaging agent developed by Collectar to be the first of its kind for broad spectrum intraoperative tumor margin illumination and non-invasive tumor imaging. CLR1502 is comprised of a proprietary phospholipid ether (PLE) analog, acting as a cancer-targeted delivery and retention vehicle attached to a fluorophore to enable real-time visualization of malignant tissue under near-infrared light.

CLR1502 is being developed for intraoperative imaging of cancer that will aid in the identification of malignant tissue during diagnostic, staging, debulking and curative cancer surgeries. In particular, the potential of CLR1502 in tumor margin illumination during oncologic resections raises the possibility that this operative aid may improve surgical outcomes.

About Collectar Biosciences, Inc.

Collectar Biosciences is developing agents to detect, treat and monitor a broad spectrum of cancers. Using a novel phospholipid ether analog (PLE) platform technology as a targeted delivery and retention vehicle, Collectar's compounds are designed to be selectively taken up and retained in cancer cells including cancer stem cells. With the ability to attach both imaging and therapeutic agents to its proprietary delivery platform, Collectar has developed a portfolio of Phase I and Phase II product candidates engineered to leverage the unique characteristics of cancer cells to "find, treat and follow" malignancies in a highly selective way. For additional information please visit www.collectar.com.

INVESTOR CONTACT

Kate McNeil, Vice President of IR, PR & Corporate Communications

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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. 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 ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, 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/A for the year ended December 31, 2014. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.
