
**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

March 30, 2015
Date of Report (Date of earliest event reported)

Celladon Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36183
(Commission
File Number)

33-0971591
(IRS Employer
Identification No.)

11988 El Camino Real, Suite 650
San Diego, CA
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: (858) 366-4288

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- ☐ 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 2.02 Results of Operations and Financial Condition.

On March 30, 2015, we announced our financial results for the fourth quarter and year ended December 31, 2014 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 and the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 and the attached Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Celladon Corporation dated March 30, 2015

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.

Celladon Corporation

Dated: March 30, 2015

By: /s/ Paul B. Cleveland

Paul B. Cleveland

President and Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Celladon Corporation dated March 30, 2015

Celladon Reports Fourth Quarter and Year-End 2014 Financial Results and Recent Highlights

— CUPID2 Topline Data Release on Track for Late April —

— Conference Call March 31, 2015 at 8:30 a.m. Eastern Time —

SAN DIEGO, CA, March 30, 2015 — Celladon Corporation (Nasdaq:CLDN), a clinical-stage biotechnology company with industry-leading expertise in the development of cardiovascular gene therapy, today announced financial results for the quarter and year ended December 31, 2014 and recent corporate highlights.

“In the last year, Celladon has made significant progress in our clinical programs and pre-commercial planning for MYDICAR, including preparations for commercial manufacturing and other long lead-time activities. Our CUPID2 trial is evaluating the use of MYDICAR to treat systolic heart failure, known as HFrEF, and we received Breakthrough Therapy designation for this program from the FDA in April of last year. The CUPID2 trial is proceeding according to plan and we look forward to un-blinding and announcing top-line data from this trial in late April 2015. Following last year’s financing activities, we are well positioned to advance our pipeline and development initiatives in 2015,” said Krisztina Zsebo, Ph.D., Chief Executive Officer of Celladon.

Fourth Quarter 2014 and Recent Corporate Highlights

MYDICAR®

- In February 2015, we reached the last subject’s last visit during the 12 month primary data analysis period in the CUPID2 study, thereby reaching the study’s primary analysis data cutoff. We remain on track to un-blind the data and announce top-line results from this study in late April 2015.
- In December 2014, we commenced work with Novasep, Inc. (Novasep) for the potential future commercial manufacture of MYDICAR drug substance (AAV1/SERCA2a), and in March 2015, we announced the execution of a development, manufacturing and supply agreement with Novasep, which, if supported by the CUPID2 data, positions the parties to continue with the process transfer, facility retrofitting, development and manufacturing activities necessary for the future commercial supply of MYDICAR drug substance. If we proceed with the ongoing activities beyond a specified termination period following the un-blinding of CUPID2, we would commit to a multi-year agreement for the future commercial supply of MYDICAR drug substance.
- In November 2014, we announced the execution of a facility construction and commercial supply agreement with Lonza Biologics, Inc. (Lonza). In exchange for a reservation fee, we have the option, exercisable during a specified timeframe and with further financial

obligation, to have Lonza commence construction of a new commercial viral therapeutics manufacturing facility, the exercise of which would commit us to a multi-year agreement for the future commercial supply of MYDICAR drug substance.

- In December 2014, we conducted initial scale up of our MYDICAR (AAV1/SERCA2a) viral manufacturing process to 2,000 liter commercial scale, completing the first demonstration batch at Lonza's Houston facility.

Fourth Quarter and Year-End 2014 Financial Results

- Cash Position: Cash, cash equivalents and investments as of December 31, 2014 were \$84.9 million.
- Research and Development Expenses: Research and development expenses were \$7.2 million and \$5.2 million for the fourth quarter of 2014 and 2013, respectively. Research and development expenses were \$22.7 million and \$16.9 million for the years ended December 31, 2014 and 2013, respectively.
- General and Administrative Expenses: General and administrative expenses were \$3.8 million and \$0.8 million for the fourth quarter of 2014 and 2013, respectively. General and administrative expenses were \$10.3 million and \$3.0 million for the years ended December 31, 2014 and 2013, respectively.
- Other Expense, Net: Other expense, net was \$0.4 million and \$0.2 million for the fourth quarter of 2014 and 2013, respectively. Other expense was \$0.8 million and \$0.1 million for the years ended 2014 and 2013, respectively.
- Consolidated Net Loss: Consolidated net loss was \$11.3 million and \$6.2 million for the fourth quarter of 2014 and 2013, respectively. Consolidated net loss was \$33.9 million and \$20.1 million for the years ended December 31, 2014 and 2013, respectively. The consolidated net loss included stock-based compensation of \$1.1 million and \$0.3 million for the fourth quarter of 2014 and 2013, respectively and \$3.3 million and \$1.4 million for the years ended December 31, 2014 and 2013, respectively.

Conference Call & Webcast

Management will host an investment community conference call to discuss financial results, provide a business update and answer questions.

Tuesday, March 31, 2015 @ 8:30am Eastern Time/5:30am Pacific Time

Domestic: 855-455-6053
International: 484-756-4307
Conference ID: 80188767
Webcast: www.celladon.com

Replays — Available through April 14, 2015

Domestic: 855-859-2056
International: 404-537-3406
Conference ID: 80188767

About Celladon

Celladon is a clinical-stage biotechnology company applying its leadership position in the field of cardiovascular gene therapy to develop novel therapies for diseases with tremendous unmet medical needs. Our lead programs target SERCA enzymes which are a family of enzymes that play an integral part in the regulation of intra-cellular calcium in all human cells. Calcium dysregulation is implicated in a number of important and complex medical conditions and diseases, such as heart failure, vascular disease, diabetes and neurodegenerative diseases. MYDICAR, the Company’s most advanced product candidate, uses gene therapy to target SERCA2a, which is an enzyme that becomes deficient in patients with advanced heart failure. Celladon’s CUPID2 trial is a 250 patient Phase 2b clinical trial evaluating the efficacy of MYDICAR in reducing the frequency of, or delaying heart failure-related hospitalizations. This randomized, double-blind, placebo-controlled, multinational trial is evaluating a single intracoronary infusion of MYDICAR versus placebo added to a maximal, optimized heart failure regimen in patients with New York Heart Association class III or IV symptoms of chronic heart failure due to systolic dysfunction, or HFrEF. The Company has received Breakthrough Therapy designation from the FDA for this MYDICAR program and expects to report results from the Phase 2b clinical trial in late April 2015. In addition, the Company conducts research and development on its mSCF gene therapy program for cardiac diseases. Celladon has also identified a number of potential first-in-class compounds addressing novel targets in diabetes and neurodegenerative diseases with its small molecule platform of SERCA2b modulators. For more information, please visit www.celladon.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, references to the expected timing of un-blinding and announcing top-line CUPID2 data; the impact of Breakthrough Therapy designation for MYDICAR; the potential future commercial production of MYDICAR drug substance by Novasep and/or Lonza, including Celladon’s decision and ability to continue activities under one or both of these agreements following the un-blinding of CUPID2 data; as well as Celladon’s ability to advance its pipeline and development initiatives in 2015. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Celladon’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with the process of conducting product development activities and clinical trials and obtaining regulatory approval to commercialize product candidates, our reliance on third parties, the need to raise additional funding when needed in order to conduct our business, and the degree of market acceptance of MYDICAR by physicians, patients, third-party payors and others in the medical community. These and other risks and uncertainties are described more fully in Celladon’s filings with the Securities and Exchange Commission, including without limitation its Form 10-Q for the quarter ended September 30, 2014. All forward-looking statements contained in this press release speak only as of the date on which they were made. Celladon undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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CONTACT:

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Condensed Consolidated Statements of Operations
(in thousands)

	Three Months Ended December 31,		Years Ended December 31,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	\$ 7,161	\$ 5,220	\$ 22,676	\$ 16,927
General and administrative	3,797	757	10,342	3,037
Total operating expenses	10,958	5,977	33,018	19,964
Loss from operations	(10,958)	(5,977)	(33,018)	(19,964)
Other income (expense), net	(383)	(202)	(835)	(127)
Consolidated net loss	<u>\$ (11,341)</u>	<u>\$ (6,179)</u>	<u>\$ (33,853)</u>	<u>\$ (20,091)</u>

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2014 (unaudited)	2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,435	\$ 7,903
Short-term investments	70,513	10,467
Prepaid expenses and other assets	3,135	180
Total current assets	88,083	18,550
Property and equipment, net	763	308
Other assets	264	2,296
Total assets	<u>\$ 89,110</u>	<u>\$ 21,154</u>
Liabilities, preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,803	\$ 2,908
Accrued clinical expenses	731	1,478
Accrued interest	71	14
Long term obligations, current portion	1	—
Convertible notes, net of discount	—	1,044
Warrant liability	—	1,116
Total current liabilities	6,606	6,560
Term loan, net of discount	10,102	—
Non-current liabilities	298	37
Preferred stock	—	65,548
Stockholders' equity (deficit)	72,104	(50,991)
Total liabilities, preferred stock and stockholders' equity (deficit)	<u>\$ 89,110</u>	<u>\$ 21,154</u>