
**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 31, 2014
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.)

12760 High Bluff Drive, Suite 240
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))
-
-

Item 2.02 Results of Operations and Financial Condition.

On March 31, 2014, we announced our financial results for the fourth quarter and full year ended December 31, 2013 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 31, 2014

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.

Dated: March 31, 2014

Celladon Corporation

By: /s/ Rebecque J. Laba

Rebecque J. Laba

Vice President, Finance and Administration

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Celladon Corporation dated March 31, 2014

Celladon Reports Fourth Quarter and Year-End 2013 Financial Results and Recent Highlights

— Conference Call Today at 4:30 p.m. Eastern Time —

SAN DIEGO, CA, March 31, 2014 – Celladon Corporation (NASDAQ: CLDN), a clinical-stage biotechnology company focused on developing novel therapies by applying its leadership position in the field of SERCA enzymes, today announced financial results for the quarter and year ended December 31, 2013.

“Celladon executed on key operational and financial objectives in 2013. With the recent completion of enrollment of our CUPID 2 trial of MYDICAR in advanced heart failure and the closing of our IPO, we are setting the stage for another productive year ahead,” said Krisztina Zsebo Ph.D., President and Chief Executive Officer.

2013 and Recent Corporate Highlights

MYDICAR

- In February 2014 we completed enrollment in the Phase 2b study with lead product candidate MYDICAR. This trial, “Calcium Up-Regulation by Percutaneous Administration of Gene Therapy In Cardiac Disease” (the “CUPID 2 Trial”) is a multinational, multicenter, double-blind, placebo-controlled, randomized study comparing a single intracoronary administration of MYDICAR versus placebo added to an optimal heart failure regimen. The primary objective is to determine the efficacy of MYDICAR in patients with ischemic or dilated cardiomyopathy and NYHA class III/IV symptoms of heart failure by reducing the frequency and/or delaying heart failure-related hospitalizations compared to placebo-treated patients. Secondary objectives include assessment of the safety of MYDICAR by determining the incidence and severity of adverse events and changes in laboratory parameters. A total of 250 patients were enrolled and data from this trial is expected in April 2015.
- In November 2013, the European Medicines Agency (EMA) indicated that if MYDICAR demonstrates a substantial and highly significant treatment effect in the advanced heart failure population, and no untoward effects attributable to MYDICAR are observed, a safety database of approximately 205-230 MYDICAR -treated subjects may be sufficient for a safety assessment to allow for acceptance of a Marketing Authorization Application, or MAA, for MYDICAR for the treatment of systolic heart failure. We therefore believe that, if the above conditions are met, a Phase 3 trial may not be required for marketing approval in Europe.
- In November 2013, the long term follow-up results from the MYDICAR CUPID 1 Trial in advanced heart failure were presented by Dr. Barry Greenberg at the American Heart Association (AHA) annual meeting. The presentation included the following highlights:
 - In the additional two year follow up period of the CUPID 1 trial, the durability of reduced cardiovascular and terminal events previously observed in the MYDICAR high dose cohort at 12 months was maintained. The risk of pre-specified recurrent cardiovascular events through the full three years of follow up was reduced by 82% in the high dose group compared to the placebo group (p=0.048).

- In addition, the survival probability over time was higher for patients in all MYDICAR dose groups compared to the placebo group, especially in the high dose group.
 - Finally, persistence of the vector DNA as assessed by qPCR testing was demonstrated in three high dose MYDICAR patients in whom a biopsy was feasible, but not from patients in the placebo or lower dose groups. Therefore, biomarker results correlated with the other beneficial effects observed in the high dose MYDICAR group.
 - No safety concerns were noted during the three year follow-up period for patients who received MYDICAR.
- In November 2013 at the American Society of Nephrology meeting, data on the role of SERCA2a deficiency in the blood vessels of dialysis patients experiencing AV fistula insertion were presented. SERCA2a was significantly decreased in the blood vessels of subjects undergoing dialysis versus subjects with normal renal function. In combination with other preclinical studies, these data support our plan to evaluate MYDICAR for improvement of AV fistula maturation failure in dialysis patients.

Small Molecule Program

- In February 2014, we entered into an option agreement with Les Laboratoires Servier (Servier). Under the terms of the agreement, we granted Servier an exclusive option to license the rights outside of the United States to our novel SERCA2b small molecule program in the field of diabetes and other metabolic disorders for a certain period. Servier's decision to exercise its option will be based upon the outcome of a series of pre-defined in vitro and in vivo studies to be performed by the parties.
- In January 2013, the United States Patent and Trademark Office (USPTO) issued a notice of allowance for U.S. Patent Application No.: 13/145,787 with claims that cover methods for identifying compounds that modulate Sarco/Endoplasmic Reticulum Calcium ATPase (SERCA) and methods for identifying compounds that modulate the SERCA/phospholamban complex using Celladon's proprietary fluorescence resonance energy transfer (FRET) assay. The patent term is expected to expire in 2030.

Recent Business Highlights

- In February 2014, we successfully completed our initial public offering (IPO) of common stock, raising net proceeds of \$44.3 million, inclusive of the over-allotment option exercised in full by the underwriters and after deducting offering expenses.
- In March 2014, we appointed Peter K. Honig, M.D., M.P.H. and Dr. Patrick Y. Yang, Ph.D. to our Board of Directors. Dr. Honig currently serves as the Head of Global Regulatory Affairs at AstraZeneca, Inc. and Dr. Yang recently retired from F. Hoffman-La Roche AG, where he served as Global Head of Pharmaceutical Technical Operations.

Fourth Quarter and Year-End 2013 Financial Results

- Cash Position: Cash, cash equivalents and investments as of December 31, 2013 were \$18.4 million. This did not include gross proceeds of \$50.6 million from the Company's IPO, which closed in February 2014. After giving effect to the net proceeds from the IPO, pro forma cash, cash equivalents and investments as of December 31, 2013 would have been \$64.3 million.
- Research and Development Expenses: Research and development expenses were \$5.2 million and \$3.3 million, respectively, for the fourth quarter of 2013 and 2012. Research and development expenses were \$16.9 million and \$13.3 million, respectively, for the years ended December 31, 2013 and 2012.
- General and Administrative Expenses: General and administrative expenses were \$0.8 million and \$0.6 million, respectively, for the fourth quarter of 2013 and 2012. General and administrative expenses were \$3.0 million and \$2.6 million, respectively, for the years ended December 31, 2013 and 2012.
- Other Income (Expense), Net: Other income (expense), net was \$(0.2) million and \$0.1 million for the fourth quarter of 2013 and 2012, respectively. Other income (expense), net was \$(0.1) million and \$0.1 million for the years ended December 31, 2013 and 2012, respectively.
- Consolidated Net Loss: Consolidated net loss was \$6.2 million and \$3.8 million for the fourth quarter of 2013 and 2012, respectively. Consolidated net loss was \$20.1 million and \$15.9 million for the years ended December 31, 2013 and 2012, respectively. The consolidated net loss included stock-based compensation of \$0.3 million and \$0.1 million for the fourth quarter of 2013 and 2012, respectively and \$1.4 million and \$0.3 million for the years ended December 31, 2013 and 2012, respectively.

Conference Call & Webcast

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

Monday, March 31, 2014 @ 4:30pm Eastern Time/1:30pm Pacific Time

Domestic:	877-359-9508
International:	224-357-2393
Conference ID:	3433760
Webcast:	www.celladon.net

Replays – Available through April 14, 2014

Domestic:	855-859-2056
International:	404-537-3406
Conference ID:	3433760

About Celladon

Celladon is a clinical-stage biotechnology company applying its leadership position in the field of calcium dysregulation by targeting SERCA enzymes to develop novel therapies for diseases with tremendous unmet medical needs. Sarco/endoplasmic reticulum Ca²⁺-ATPase, or SERCA, enzymes 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, which is a clinical syndrome characterized by poor heart function, resulting in inadequate blood flow to meet the body's metabolic needs, as well as diabetes and neurodegenerative diseases. Celladon's therapeutic portfolio for diseases characterized by SERCA enzyme deficiency includes both gene therapies and small molecule compounds. MYDICAR, the Company's most advanced product candidate, uses gene therapy to target SERCA2a, which is an enzyme that becomes deficient in patients with heart failure. In addition, Celladon has 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.

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, statements regarding Celladon's anticipated timing for reporting results from CUPID 2, the extent of the role MYDICAR may have in improving the clinical course of heart failure patients or decreasing the rate of AV fistula maturation failure in dialysis patients, and whether a phase 3 trial for MYDICAR will be required by applicable regulatory authorities. 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-K for the year ended December 31, 2013. 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.

#

CONTACT:

Fredrik Wiklund
Vice President, Corporate Development and Investor Relations
(858) 432-7215
fwiklund@celladon.net

Michael Rice
LifeSci Advisors LLC
(646) 597 6987

Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2013	2012	2013	2012
	(unaudited)			
Operating expenses:				
Research and development	\$ 5,220	\$ 3,309	\$ 16,927	\$ 13,314
General and administrative	757	646	3,037	2,631
Total operating expenses	<u>5,977</u>	<u>3,955</u>	<u>19,964</u>	<u>15,945</u>
Loss from operations	(5,977)	(3,955)	(19,964)	(15,945)
Other income (expense), net	(202)	121	(127)	74
Consolidated net loss	<u><u>\$ (6,179)</u></u>	<u><u>\$ (3,834)</u></u>	<u><u>\$ (20,091)</u></u>	<u><u>\$ (15,871)</u></u>

Condensed Consolidated Balance Sheets
(in thousands)

	December 31,	
	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,903	\$ 13,841
Short-term investments	10,467	18,808
Prepaid expenses and other assets	180	288
Total current assets	<u>18,550</u>	<u>32,937</u>
Long-term investments	—	2,862
Property and equipment, net	308	122
Other assets	2,296	8
Total assets	<u><u>\$ 21,154</u></u>	<u><u>\$ 35,929</u></u>
Liabilities, preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,908	\$ 1,134
Accrued clinical expenses	1,478	644
Accrued interest	14	—
Convertible notes, net of discount	1,044	—
Warrant liability	1,116	—
Total current liabilities	<u>6,560</u>	<u>1,778</u>
Deferred rent	37	28
Redeemable non-controlling interest	—	4,814
Preferred stock (a)	65,548	57,725
Stockholders' deficit	(50,991)	(28,416)
Total liabilities, preferred stock and stockholders' deficit	<u><u>\$ 21,154</u></u>	<u><u>\$ 35,929</u></u>

- (a) All preferred stock converted to common stock as a result of the Company's IPO in February 2014. Following the completion of the IPO, including the over-allotment, there are 18,500,015 shares of common stock outstanding.