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## Celladon Corp. (CLDN)

# Q3 Fundraising Supports Manufacturing and Expansion Plans for Mydicar, Reiterate OUTPERFORM

- CLDN reported a Q3 net loss of \$8.4M, or (\$0.40) per share, below (\$0.38) consensus, but matching our estimates. Cash and equivalents at the end of Q3 stood at \$95.1M, boosted during the quarter by a ~\$41M secondary offering and a \$10M loan. We expect the cash will take CLDN through 2016.
- CLDN readies commercial production of Mydicar with Lonza agreement. In Q3 CLDN expanded its relationship with Lonza, which has been producing the Mydicar supply for clinical studies, into a strategic collaboration for commercial scale production of Mydicar. As part of the agreement, Lonza will begin preconstruction activities for a dedicated facility for Mydicar production in Portsmouth NH. CLDN has the option to trigger construction of the facility and a multi-year supply commitment, and if it does so, then Lonza has agreed to take a \$10M equity stake in CLDN.
- Mydicar is set to be explored in additional indications in 2015. Next year, CLDN plans to begin a Ph I/II study in advanced systolic HF patients with nAbs to the AAV1 vector used in Mydicar and a Ph IIa trial in ESRD patients undergoing surgery for AV fistula creation. Although we do not currently model for sales in these indications, the studies could potentially expand the patient population eligible to receive Mydicar and explore its usage in areas outside heart failure.
- CUPID2 readout in April 2015 remains the major catalyst for the stock. During Q3 the independent DMC completed its fourth review of CUPID2 and recommended continuing the study. We view the recommendation as a reflection of Mydicar's benign safety profile, and await the efficacy readout next April.
- Reiterate OUTPERFORM and \$17 price target. Our price target of \$17 is derived from applying a 6 multiple to estimated 2020 sales in new heart failure patients, discounted by 35% annually, supplemented by the present value of sales in existing heart failure patients (also discounted by 35% annually).
- Risks to the achievement of our price target include clinical failure of MYDICAR, failure to achieve regulatory approval and failure to achieve sales and earnings estimates.

FYE Dec	2013A		2014E			2015E	
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		0.0A		\$0.0A	0.0E		\$0.0E
Q2 Jun	0.0A	0.0A		0.0A	0.0E		0.0E
Q3 Sep	0.0A	0.0A		0.0A	0.0E		0.0E
Q4 Dec	0.0A	0.0E		0.0E	0.0E		0.0E
Year*	0.0A	0.0E		\$0.0E	0.0E		\$0.0E
Change							
	2013A		2014E			2015E	
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		(\$0.60)A		(\$0.60)A	(\$0.38)E	(\$0.42)E	(\$0.42)E
Q2 Jun		(\$0.38)A		(\$0.38)A	(\$0.32)E	(\$0.34)E	(\$0.34)E
Q3 Sep	(\$0.45)A	(\$0.40)A		(\$0.38)A	(\$0.30)E	(\$0.32)E	(\$0.32)E
Q4 Dec	(\$0.51)A	(\$0.37)E	(\$0.41)E	(\$0.38)E	(\$0.28)E	(\$0.30)E	(\$0.32)E
Year*	(\$1.67)A	(\$1.75)E	(\$1.79)E	(\$1.66)E	(\$1.27)E	(\$1.38)E	(\$1.36)E
P/E							
Change		-5%			27%		

Consensus estimates are from Thomson First Call.

November 12, 2014

Price

\$12.36

Rating

### OUTPERFORM

## 12-Month Price Target **\$17**

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Company Information	
Shares Outst (M)	23.3
Market Cap (M)	\$288.0
52-Wk Range	\$7.45 - \$17.16
Book Value/sh	\$2.62
Cash/sh	\$4.08
Enterprise Value (M)	\$192.8
LT Debt/Cap %	0%
Cash Burn (M)	\$34.2

#### **Company Description**

Celladon Corp. is based in San Diego, Ca. and is focused on the development of MYDICAR, a gene therapy product for increasing SERCA2a expression, currently in the Phase IIb CUPID 2 trial in advanced systolic heart failure.



Source: Thomson Reuters

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<sup>\*</sup> Numbers may not add up due to rounding.



CLDN also reported in-licensing worldwide rights to gene therapy applications for the membrane-bound form of the Stem Cell Factor (SCF) gene for treatment of cardiac ischemia. SCF is a critical cytokine that contributes to cell migration, proliferation and survival, and its expression has been found to increase following a heart attack. SCF is thought to play a role in cardiac repair, and preclinical studies have shown that SCF gene transfer was associated with improved cardiac function in a swine model of ischemic cardiomyopathy. CLDN plans to develop gene therapy vectors to evaluate the potential of delivering SCF in patients who have suffered cardiac damage.

#### Milestones

April 2015 Data from Phase 2b CUPID trial

early 2015 Servier to decide on whether to exercise its option to license international rights to small molecule SERCA2b program

in diabetes

2015 start Phase I/II study of MYDICAR in nAb-positive systolic heart failure patients

2015 start Phase 2a trial for AV fistula maturation failure in ESRD patients

#### **Investment Summary**

Celladon Corporation (CLDN) is a biotechnology company focused on the development of MYDICAR for cardiovascular diseases characterized by deficiencies in the SERCA enzyme. Its lead clinical program is MYDICAR, a gene therapy designed to restore normal levels of the SERCA enzyme, in the Phase IIb CUPID 2 trial for the treatment of advanced systolic heart failure. MYDICAR could also be efficacious in treating other serious cardiovascular diseases, including diastolic heart failure, advanced heart failure in patients on an LVAD, pulmonary arterial hypertension, and AV-fistula maturation failure. CLDN also has small molecule SERCA modulators in preclinical development for diabetes and neurodegenerative conditions. The EMA has indicated that CUPID 2 could serve as the basis for an MAA application, and there is a possibility that the ongoing Phase IIb study could be sufficient for early approval in the US.

#### **Financial Model**

11/12/2014 Ticker: (CLDN:Nasdaq) Celladon Corporation

#### Wedbush PacGrow Life Sciences

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	2012A	2013A	Q1	Q2	Q3	Q4	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:													
US Product Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$111,108	\$411,839
ex-US Product Sales	\$0	0	\$0	\$0	\$0	\$0	0	0	0	0	56,463	231,272	388,676
Grant Revenue	\$0	0	\$0	\$0	\$0	\$0	0	0	0	0	0	0	0
Total Revenues	0	0	0	0	0	0	0	0	0	0	56,463	342,380	800,515
Cost and Expenses:													
Cost of Sales	0	0	0	0	0	0	0	0	0	0	0	11,111	41,184
R&D	13,314	16,927	5,218	4,981	5,316	5,422	20,937	22,796	26,562	29,992	32,465	35,141	38,037
SG&A	2,631	3,037	1,706	2,024	2,815	2,871	9,416	11,981	12,497	13,331	22,607	43,241	118,564
Total Operating Expenses	15,945	19,964	6,924	7,005	8,131	8,294	30,354	34,776	39,059	43,324	55,072	89,492	197,786
Operating Income (Loss)	(15,945)	(19,964)	(6,924)	(7,005)	(8,131)	(8,294)	(30,354)	(34,776)	(39,059)	(43,324)	1,391	252,888	602,729
Net Interest Income (Expense)	(73)	58	(51)	21	(235)	634	369	3,174	4,484	5,004	4,111	6,506	16,963
Other non-operating Income (Expense)	147	0	(187)	(8)	8	0	0	0	0	0	0	0	0
Income Before Income Taxes	(15,871)	(19,906)	(7,162)	(6,992)	(8,358)	(7,659)	(29,984)	(31,602)	(34,576)	(38,320)	5,502	259,393	619,692
Provision for Income Taxes	0	0	0	0	0	0	0	0	0	0	658	9,383	195,224
Net Income (Loss)	(15,871)	(19,906)	(7,162)	(6,992)	(8,358)	(7,659)	(29,984)	(31,602)	(34,576)	(38,320)	4,844	250,010	424,468
GAAP EPS	(1.58)	(1.67)	(0.60)	(0.38)	(0.40)	(0.37)	(1.75)	(1.27)	(1.10)	(1.12)	0.14	7.12	12.09
Total Shares Outstanding	10,262	12,035	18,500	18,534	23,298	23,323	23,323	30,898	34,973	37,573	37,648	37,648	37,648
Cash Burn	-	(15,074)	(9,927)	(7,304)	(7,188)	(9,758)	(34,177)	(34,413)	(38,707)	(42,973)	2,356	237,326	561,851
Cash Balance	32,649	18,370	57,629	51,172	95,122	86,248	86,248	134,660	164,605	162,003	154,812	388,906	771,556

Source: Wedbush Securities, Inc.



#### Analyst Biography

David Nierengarten, Ph.D.

David is an Analyst covering stocks in the Biotechnology/Biopharmaceuticals/BioDefense sector. His prior sell-side research experience at Robert W. Baird & Co. covered biotechnology companies of all market capitalizations, with a focus on oncology and rare diseases.

David received his B.S. (Biochemistry) from the University of Wisconsin-Madison and Ph.D. (Molecular and Cell Biology) from the University of California-Berkeley.

David's Edge: David's early stage venture capital investing experience gives him a balanced perspective on developmental-stage biotechnology companies and their ultimate risk/reward potential. His experience on the other side of that equation in a clinical-stage, venture backed biotechnology company provides him with insights into corporate operations. The combination of experiences creates a focus on value creation in this event-driven space.

#### **Analyst Certification**

I, David M. Nierengarten, Ph.D., Heather Behanna, Ph.D., Dilip Joseph, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).\*

Rating Distribution (as of September 30, 2014)	Investment Banking Relationships (as of September 30, 2014)
Outperform:54%	Outperform:23%
Neutral: 43%	Neutral: 1%
Underperform: 3%	Underperform: 0%

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#### Wedbush Equity Research Disclosures as of November 12, 2014

Company	Disclosure
Celladon Corp.	1,3,4,5,7

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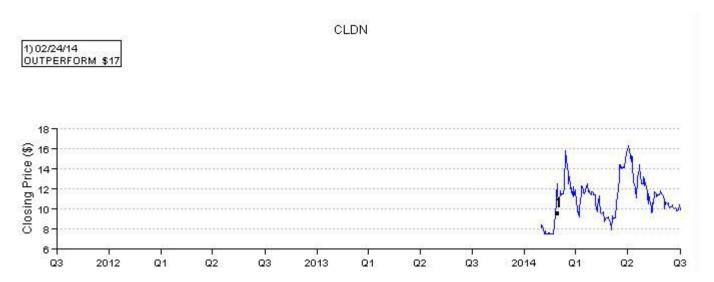
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