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Celladon Corp. (CLDN - OUTPERFORM): Analyst Day Takeaway: New Applications for MYDICAR in AV Fistula Maturation Failure and Plasmapheresis, Reiterate OUTPERFORM

Price: $10.49 **12-Month Price Target: $17**

- **We attended the Celladon Investor and Analyst Day in New York City, where management focused on additional applications beyond heart failure for its MYDICAR gene therapy to correct SERCA2a enzyme deficiency.** Specifically, CEO Krisztina Zsebo and co-founder Dr. Roger Hajjar (Director of the Cardiovascular Research Center and Professor of Medicine at Mount Sinai School of Medicine) discussed the potential of MYDICAR to prevent maturation failure of arteriovenous (AV) fistulas, which are artificial passageways between an artery and vein created by surgeons as the preferred method of vascular access for hemodialysis in end-stage renal failure patients. Maturation failure, which occurs in about half of all AV fistulas, is characterized by a SERCA2a deficiency in vascular smooth muscle cells leading to stenosis. Prior research in a human *ex vivo* model of arterial thickening has shown that SERCA2a gene transfer reduced stenosis and prevented vascular remodeling. With no approved therapies for the indication and a large unmet need, we believe preventing AV fistula maturation failure is a promising new therapeutic area for MYDICAR and anticipate further details about the clinical development plan to be made available over the coming year.

- **The presentation by Dr. Hajjar summarized the therapeutic effect MYDICAR has demonstrated thus far in systolic heart failure, and reinforced our belief in the therapy's potentially transformative benefit.** Dr. Hajjar spoke of the central role SERCA2a deficiency has on the progression of heart failure (regardless of etiology) and reviewed the results of the Phase IIa CUPID trial, in which high-dose ($1x10^{13}$ DNase-resistant particles) MYDICAR plus optimal therapy outperformed the placebo plus optimal therapy arm in survival and rates of clinical events and recurrent hospitalization. Given that the latter measure serves as the primary endpoint in the potentially pivotal Phase IIb CUPID2 trial, we remain confident in MYDICAR's chance of success in systolic heart failure.

- **The company is also seeking to expand the patient population for MYDICAR to those who have pre-existing neutralizing antibodies to AAV vectors.** An estimated 60% of heart failure patients have neutralizing antibodies (nAbs) to AAV1, resulting in a large patient population that is ineligible for MYDICAR therapy. CLDN said they will examine the clinical utility of plasmapheresis in reducing the level of nAbs in patients. Plasmapheresis, which involves the selective removal of plasma (which contains the nAbs) from blood circulation, is routinely used in patients with autoimmune disorders or who are undergoing transplants. CLDN presented pilot data from three patients which demonstrated that plasmapheresis reduced nAb levels in all patients (see Fig. 1). In one patient, nAb titer levels fell below 1:2, which would make them eligible for MYDICAR therapy. CLDN intends to conduct their own prospective studies to examine the magnitude and timing of nAb reduction following plasmapheresis, and success in this initiative could represent a relatively straightforward method to greatly expanding the potential market for MYDICAR.

Figure 1: Reduction in Neutralizing Antibody Titers following Plasmapheresis

Days post Plasmapheresis		AAV1 Neutralizing Antibody Titer
Patient #1	0	1:32
	13	1:2
Patient #2	0	1:4
	15	1:2
Patient #3	0	1:8
	9	<1:2

Source: Celladon Corp.

- **We do not include the AV fistula and plasmapheresis programs in our current valuation.** The lead catalyst for CLDN remains the read-out of the CUPID2 trial, which management reiterated was on track to be available in April 2015.

- **Next, the company will report Q1:14 earnings on May 13.** We estimate the company will report a quarterly loss of $0.61 per share and a Q1 ending cash balance of $55.5M. We believe current cash levels are sufficient to take them through the CUPID2 readout.

- **Reiterate OUTPERFORM rating and $17 price target.** Our price target 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.

Analyst Certification
I, David M. Nierengarten, Ph.D., Gregory R. Wade, Ph.D., Christopher N. Marai, 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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Company	Disclosure
Celladon Corp.	1,3,5,7

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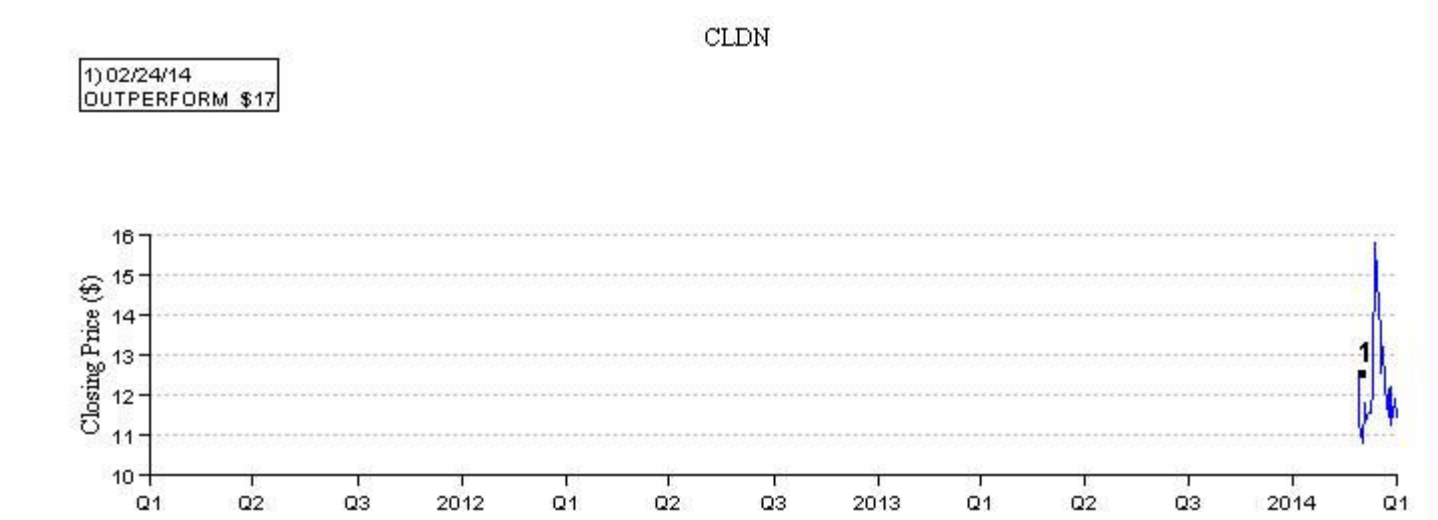

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