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## Celladon Corp. (CLDN - OUTPERFORM): MYDICAR Becomes First Gene Therapy to be Granted Breakthrough, Reiterate OUTPERFORM

Price: \$12.00

12-Month Price Target: \$17

- **The FDA granted MYDICAR Breakthrough Therapy designation for reducing hospitalizations for heart failure in advanced, chronic heart failure patients who are negative for neutralizing antibodies to the AAV1 viral vector.** Breakthrough designation grants a product candidate all of the benefits of Fast Track designation, including an expedited development and review process, plus direct guidance from FDA on clinical development. The designation is granted to drug candidates that treat a serious condition and where “preliminary evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint over available therapies”.
- **We believe granting of Breakthrough designation increases the likelihood that the ongoing Phase IIb CUPID 2 trial in advanced systolic heart failure could be sufficient for approval.** In our view, if FDA were to require a Phase III trial after positive CUPID 2 results, the overall approval timeline should still be shortened, with expedited reviews of safety, CMC, and/or other portions of the filing. Recall, CLDN currently has a Special Protocol Assessment (SPA) in place with the FDA agreeing to a single, 572-patient Phase III trial using the same endpoint as CUPID 2 (time to recurrent HF-related hospitalizations in the presence of terminal events), and our base case for US approval is after CLDN conducts a Phase III trial.
- **As the first gene therapy product to receive Breakthrough designation from the FDA, we believe that the decision reflects a greater acceptance at the agency towards gene therapy and an understanding of the benefits these treatments have in disorders with a significant unmet need.**
- **Reiterate OUTPERFORM rating 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.

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**Outperform:** Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

**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).\*

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Underperform: 3%	Underperform: 0%

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**Wedbush Equity Research Disclosures as of April 10, 2014**

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

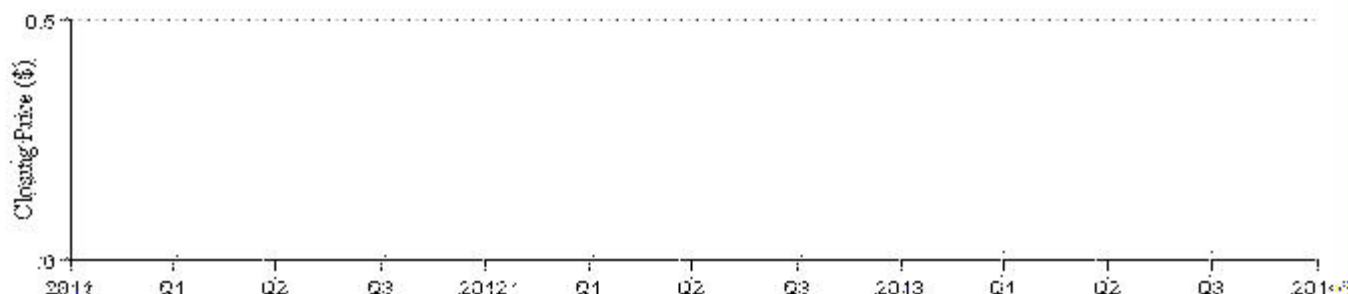
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CLDN



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