

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

October 3, 2013

Via E-mail
Krisztina Zsebo, Ph.D.
President and Chief Executive Officer
Celladon Corporation
12760 High Bluff Drive, Suite 240
San Diego, California 92130

Re: Celladon Corporation

Confidential Draft Registration Statement on Form S-1 Submitted on September 6, 2013

File No. 377-00304

Dear Dr. Zsebo:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### General

- 1. Please file all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.
- 3. Please supplementally provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act

of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

4. Comments to your application for confidential treatment will be delivered under separate cover.

# Prospectus Summary Overview, page 1

- 5. Please define the following terms:
  - Heart failure;
  - Systolic heart failure;
  - Diastolic heart failure; and
  - AV fistula maturation failure.

#### Risk Factors

We may find it difficult to enroll patients . . ., page 16

6. We note that you have significant obstacles in the timely recruitment and enrollment of eligible patients in your CUPID 2 trial. We also note that the FDA has approved a 572 patient Phase 3 trial. Please expand your disclosure to discuss the difficulty of enrolling patients for a 572 patient Phase 3 trial.

## The results from our CUPID 2 trial may not be sufficiently robust . . ., page 19

7. We note on page 3 that the FDA has discussed proceeding to a Phase 3 clinical trial with high-dose MYDICAR, and that the FDA has approved a 572 patient Phase 3 trial. We also note on page 19 that that if the FDA or the EMA requires additional studies, including Phase 3 trials, you would incur increased costs and delays in the marketing approval process, which would require you to expend more resources than you have available. Please revise your disclosure on these pages and throughout the registration statement, as applicable, to clarify that the FDA currently requires you to complete the Phase 3 trial. Additionally, please expand your disclosure to include any communications with the FDA or reasoning that leads you to believe that a Phase 3 clinical trial may not be necessary.

#### We intend to rely on third parties to produce our viral vectors, page 26

8. We note that you filed your manufacturing services agreement with Lonza as Exhibit 10.23 and that on page 80 you state that you have entered into an agreement with Lonza. We also note that you state that you have entered into a non-binding letter of intent with Lonza. Please clarify if you have a binding agreement with Lonza at this time. Additionally, to the extent material, please disclose the material terms of your

manufacturing agreement, including the material rights and obligations of the parties, duration of the agreement and termination provisions.

# Changes in U.S. patent law could diminish the value of patents, page 47

9. We note that you state that the recent U.S. Supreme Court rulings have created uncertainty with respect to the value of patents. Please identify any of your licensed or owned patents that may be vacated or adversely affected by the U.S. Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* 

#### Use of Proceeds, page 56

10. We note that you state that you believe funding from this offering will allow you to complete your CUPID 2 clinical trial and initiate your planned AAV1 NAb positive and viral shedding trials, as well as the development of manufacturing capabilities for the commercial production of MYDICAR, including commercial scale-up and validation and automation of our companion diagnostic. Please amend your disclosure to include an approximate amount of the proceeds you plan to allocate to the CUPID 2 clinical trial, each of the AAV1 Nab positive and viral shedding trials, and the development of manufacturing capabilities. Additionally, please expand your disclosure to state the stage of development of your planned AAV1 NAb positive and viral shedding trials that you expect to reach using the allocated proceeds.

<u>Management's Discussion and Analysis of Financial Condition and Results of Operations Financial Overview</u>

Determination of the Fair Value of Common Stock, page 71

- 11. We will further evaluate your accounting for stock compensation and related disclosure when your IPO price has been set. Please expand your disclosure to address the following:
  - In the last paragraph on page 71 you discuss the cost approach. Please revise your disclosure to clarify whether you utilized that approach. If so, please explain to us separately how it is relevant in your circumstances.
  - Disclose how you determined that a cost of capital of 26% and a discount for lack of marketability of 15% were appropriate at June 30, 2013.
  - Please disclose the reassessed assumptions used in the April 25, 2013 estimated valuation of the Company's common stock.
  - Once you can reasonably estimate the IPO price, qualitatively and quantitatively discuss each significant factor contributing to the difference between the latest valuation and the estimated IPO price.
  - Continue to update your disclosure for all equity related transactions, including any options, warrants, or convertible note or preferred stock issuances, through the effective date of the registration statement.

12. In the penultimate paragraph on page 71 you disclose that you considered and relied upon an appraisal of the value of your common stock as of January 31, 2012 that was prepared by an independent third-party valuation specialist. In the fifth paragraph on page 73 you disclose that you utilized an appraisal of the value of your common stock as of June 30, 2013 that was also prepared by an independent third-party valuation specialist. These statements appear to convey full reliance upon these valuation reports. If so, please revise your disclosure to indicate the names of these valuation specialists, identify them as experts and have them provide their consents. Otherwise, please revise your disclosure to take responsibility for the valuations and indicate how you utilized them in assessing fair value of your common stock. Please see Question 233.02 of the Compliance and Disclosure Interpretations for the Securities Act Rules.

#### **Business**

## MYDICAR for Heart Failure, page 86

13. We note that you disclose instances in which an additional IND for MYDICAR would need to be filed for a specific indication. Please disclose the INDs you have submitted for MYDICAR. Additionally, please provide the date(s) filed and the identity of the filer if different from the company.

# Clinical Events in CELL-001 Phase 2a, page 92

14. We note on page 93 that you hypothesize that low- and mid-dose groups demonstrate a delay to onset of clinical events due to the short-term increase in blood flow to the heart after MYDICAR therapy. Please expand on this disclosure to explain the reason for the short-term increase in blood flow after MYDICAR therapy compared to the placebo.

#### CUPID 1 (CELL-001) Long-term Follow-up, page 94

15. We note on page 95 that you have tested for the presence of the vector DNA in patients after treatment. Please disclose if you are aware of any observations that would suggest that the high-dose treatment of MYDICAR would also have limited durability based on your biopsy testing, and information gained from the low- and mid-dose groups.

# MYDICAR-HF/pEF MYDICAR for Heart Failure with Preserved Ejection Fraction (Diastolic Heart Failure), page 100

16. We note on page 82 that MYDICAR delivers the gene for the SERCA2a enzyme. We also note on page 88 that calcium is sequestered back in the SR by the SERCA2a enzyme leading to muscle relaxation. We note on page 89 and 100 that you state that SERCA2a deficiency is a cause of diastolic heart failure. We also note that you are developing MYDICAR to target diastolic heart failure. Please clarify how MYDICAR can be used to target diastolic heart failure.

# <u>Patent Protection for MYDICAR</u> Composition of MYDICAR, page 105

17. We note that you have in-licensed two patent families from AmpliPhi and AskBio LLC regarding the composition of MYDICAR. We also note that the license agreement with AskBio is filed as Exhibit 10.17 as a non-exclusive agreement. Please amend your disclosure to state if these are exclusive or non-exclusive licenses.

#### Manufacture of AAV Vectors, page 105

18. We note on page 106 that you have pending patent applications in the United States and several foreign countries relating to the Manufacture of AAV Vectors. Please clarify if these patent applications are covered in your license agreement or if you control them directly. Additionally, please list the material non-U.S. countries in which these patents are pending.

#### Use of SERCA2a for the Treatment of Heart Failure, page 106

19. We note on page 106 that you have licensed certain patents related to the use of SERCA2a for the treatment of heart failure. Please disclose the licensor that owns these patents.

## International Patent Protection for MYDICAR, page 106

20. We note on page 106 that, in addition to your patent coverage in the U.S., you have or have licensed related patents and patent applications abroad. Please identify any patents that cover material non-U.S. jurisdictions and provide the jurisdiction(s), expiration date(s) and other relevant information comparable to your disclosures regarding your U.S. patent portfolio.

# Methods of Treating Stenosis, page 106

- 21. We note on page 106 that you in-license patents related to using SERCA2a genes to reduce stenosis. Please disclose the licensor that owns these patents. Additionally, if this license agreement is material to your company, please disclose all of the material terms agreed to by the parties. This includes, but is not limited to:
  - material payment terms, including royalties owed;
  - the relevant intellectual property covered and rights conveyed as to such property;
  - the duration of the agreement; and
  - the material termination provisions.

Please file this agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please provide us with an analysis supporting your determination that the agreement is not material to the company.

### Methods of Treating Pulmonary Arterial Hypertension, page 107

- 22. We note on page 107 that you are the co-owner of a patent application for patents to treat pulmonary arterial hypertension. Please disclose the other co-owner. Additionally, please disclose if you have entered into an agreement with the co-owner. If this agreement is material to your company, please disclose all of the material terms agreed to by the parties. This includes, but is not limited to:
  - material payment terms, including royalties owed;
  - the relevant intellectual property covered and rights conveyed as to such property;
  - the duration of the agreement; and
  - the material termination provisions.

Please file this agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please provide us with an analysis supporting your determination that the agreement is not material to the company.

# Methods of Treating Heart Arrhythmia, page 107

- 23. We note on page 107 that you in-license a patent family assigned to the U.S. National Institutes of Health. If this agreement is material to your company, please disclose all of the material terms agreed to by the parties. This includes, but is not limited to:
  - material payment terms, including royalties owed;
  - the relevant intellectual property covered and rights conveyed as to such property;
  - the duration of the agreement; and
  - the material termination provisions.

Please file this agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please provide us with an analysis supporting your determination that the agreement is not material to the company.

#### License Agreement with The Regents of the University of California, page 108

24. We note that the license agreement with the UC will terminate upon the expiration of the applicable UC patent rights. Please disclose the expiration dates of the applicable UC patent rights under the agreement.

#### Sublicense Agreement and Amended and Restated License Agreement with AmpliPhi, page 109

25. We note that you are obligated to pay to AmpliPhi a low single-digit percentage royalty based on net sales of any companion diagnostic covered by a licensed patent sold by you and that you are obligated to pay to AmpliPhi all royalty payments that become due to UPenn, including a low single-digit tiered percentage royalty on net sales of any companion diagnostic sold by you. Please clarify that these two royalty payments are separate obligations.

# Non-Exclusive License Agreement with Virovek, page 111

26. We note that the license agreement with Virovek will terminate upon the expiration of your royalty payment obligations or 10 years from the date of first commercial sale in some instances. Please amend your disclosure to state the time that your licensed patents expire.

# Principal Stockholders, page 156

- 27. Please revise the table on page 157 to include the shares held by Enterprise Partners entities as also held by Dr. Senyei; the shares held by Lundbeckfond Invest A/S as also held by Dr. Kördel; the shares held by GBS Bioventures IV as also held by Dr. Funder; the shares held by MPM Capital entities as also held by Mr. Foley; the shares held by H&Q Funds as also held by Dr. Omstead, the shares held by Cooperatief LSP IV UA as also held by Dr. Azzam, the shares held by Novartis Bioventures Ltd. as also held by Dr. Silverman, and the shares held by Pfizer Inc. as also held by Dr. Dalton. Please also include these shares in the total aggregate shares of all executive officers and directors as a group.
- 28. For each of the entities affiliated with Venrock Partners, which are also beneficial owners of shares, please disclose the natural person or persons who exercise the voting and/or dispositive powers with respect to such shares.

# Shares Eligible for Future Sale Lock-Up Agreements, page 165

- 29. Once available, please file copies of the lock-up agreements.
- 30. Please state the number of shares that are subject to a lock-up.

# Notes to the Financial Statements Note 5. Commitments and Contingencies, page F-19

- 31. Please disclose the term length of the patent license agreement with the Regents of the University of Minnesota and any other significant obligations and terms of the agreement. Disclose if the agreement encompasses a manufacturing agreement.
- 32. Please revise your disclosures to provide an estimate of your known payment obligations for each license and sublicense agreement disclosed. For example, regarding the AmpliPhi Sublicense agreement disclosures state the Company is obligated to pay an annual sublicense maintenance fee of \$310,000 and in the University of Minnesota the annual license fee is \$120,000. Also, include this information in your "Contractual Obligations and Commitments" disclosure in MD&A and quantify there your potential milestone obligations.
- 33. Please revise your disclosures to state how the annual maintenance and annual license payments for the disclosed license and sublicense agreements were accounted for in your financial statements.
- 34. For each of your agreements, please revise your disclosures to state what milestones, if any, have been achieved by the Company and milestone payments made or accrued for each of the periods presented and cumulatively year to date.

# Note 6. Preferred Stock and Stockholders' Equity (Deficit), page F-22

35. Please revise your disclosure to clarify why your Junior preferred stock is classified in the mezzanine on your balance sheet. Although you indicate in your policy disclosure on page F-14 that you classify stock that is redeemable outside your control in the mezzanine, your redemption rights disclosure on page F-23 only appears to apply to your Series A-1 preferred stock.

#### Note 7. Income Taxes, page F-26

36. Please tell us your consideration of the guidance in ASU 2013-11 regarding the potential impact on your accounting for unrecognized tax benefits and your net operating loss and research and development credit carryforwards deferred tax assets. To the extent appropriate, please revise your disclosure of recently issued accounting pronouncements to include this pronouncement.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy

(http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Christine Allen at (202) 551-3652 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Matthew Jones at (202) 551-3786, John Krug at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Jason Kent, Esquire Cooley LLP 4401 Eastgate Mall San Diego, California 92121