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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## Form 8-K

### CURRENT REPORT

### PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (date of earliest event reported):

**April 18, 2005**

## PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation)

**000-19756**

(Commission File No.)

**94-3023969**

(I.R.S. Employer Identification  
No.)

**34801 Campus Drive**

**Fremont, California 94555**

(Address of principal executive offices)

Registrant's telephone number, including area code:

**(510) 574-1400**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ 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))
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#### Item 8.01 Other Events.

On April 18, 2005, Protein Design Labs, Inc. ("PDL") issued a press release announcing results from a Phase II clinical trial of ularitide for decompensated congestive heart failure. A copy of PDL's press release is attached hereto as Exhibit 99.1.

#### Item 9.01 Financial Statements and Exhibits.

##### (c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Protein Design Labs, Inc. on April 18, 2005.

#### 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.

Date: April 19, 2005

**PROTEIN DESIGN LABS, INC.**

By: /s/ Sergio Garcia-Rodriguez  
**Sergio Garcia-Rodriguez**



www.pdl.com



For Immediate Release

Contact:

James R. Goff  
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Corporate Communications  
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**PROTEIN DESIGN LABS REPORTS POSITIVE RESULTS IN  
PHASE II CLINICAL TRIAL (SIRIUS II) OF ULARITIDE FOR DECOMPENSATED  
CONGESTIVE HEART FAILURE**

Fremont, Calif., April 18, 2005 – Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported positive results from a Phase II clinical study, known as the SIRIUS II trial, of the natriuretic peptide ularitide in patients with decompensated congestive heart failure (DHF).

The SIRIUS II trial was a randomized, double-blind, placebo-controlled clinical trial conducted at 19 centers in Europe. Primary endpoints in the study were change in pulmonary capillary wedge pressure (PCWP) and change in dyspnea (shortness of breath) score, both at six hours. A total of 221 patients were randomized equally to receive ularitide 7.5, 15, or 30 ng/kg/min given intravenously as a 24-hour infusion, or placebo. In the assessment of the primary endpoints, ularitide significantly reduced PCWP ( $p < 0.05$ ) and improved dyspnea score ( $p < 0.05$ ) in all three dose groups compared to placebo. The main adverse events through day three were dose-dependent decreases in blood pressure compared to placebo. Serum creatinine levels were unchanged during and after ularitide treatment when compared to placebo. The incidence of serious adverse events was similar for all three treatment groups and the placebo group.

“Based on these encouraging data, we intend to further study ularitide as a potential treatment for patients with decompensated congestive heart failure,” said Steven Benner, M.D., Senior Vice President and Chief Medical Officer, PDL. “We have submitted an abstract summarizing these data for possible presentation at the Scientific Meeting of the Heart Failure Society of America to be held September 18-21 at Boca Raton, Florida. We may additionally submit an abstract to the European Society of Cardiology Congress to be held in Stockholm, Sweden, September 3-7.” Following these potential presentations, PDL expects to discuss its development strategy and future study timelines during an R&D Update to be scheduled for late September or early October 2005 in New York.

The SIRIUS II clinical trial was conducted by CardioPep Pharma GmbH. PDL has acquired from CardioPep, through a license agreement between CardioPep and ESP Pharma, Inc., PDL’s wholly-owned subsidiary, exclusive rights to conduct all subsequent development and exclusive marketing rights for ularitide for all indications in the United States, Canada, the European Union and Switzerland. To date, the clinical development of ularitide has taken place in Europe. A U.S. IND has not yet been filed by CardioPep.

**About Ularitide**

Ularitide is processed from the same gene that produces atrial natriuretic peptide in the heart. The peptide was first isolated by scientists affiliated with the group of Wolf-Georg Forssmann at Heidelberg University, and has been developed by a German company, CardioPep Pharma GmbH.

In a previous Phase IIa study in patients with DHF, referred to as the SIRIUS I trial, ularitide was shown to enhance natriuresis and diuresis, and to decrease central venous pressure. The SIRIUS I trial was a double-blind, placebo-controlled ascending-dose study. This trial enrolled 24 patients who received a 24-hour infusion of placebo, or in ascending dose cohorts, 7.5, 15 or 30 ng/kg/min of ularitide. The study was primarily intended to assess safety, but evidence of hemodynamic activity was observed at the two higher dose levels when assessed at six hours. There was no apparent difference in adverse events across the four treatment groups. Results of the SIRIUS I study are now in press in the American Heart Journal.

**About Decompensated Congestive Heart Failure (DHF)**

DHF is a serious medical condition in which the heart is unable to maintain adequate circulation of blood in the tissues of the body or to pump out the venous blood returned to it by the venous circulation. In the United States alone, there are approximately one million hospitalizations per year for decompensated congestive heart failure.

**About Protein Design Labs**

Protein Design Labs is a fully-integrated biopharmaceutical company focused on the development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products. PDL markets several pharmaceutical products in the United States through its wholly-owned subsidiary, ESP Pharma, Inc. Further information on PDL is available at [www.pdl.com](http://www.pdl.com) or by contacting James R. Goff, Senior Director, PDL Corporate Communications, (510) 574-1421 or [jgoff@pdl.com](mailto:jgoff@pdl.com).

The foregoing contains forward-looking statements involving risks and uncertainties and PDL’s actual results may differ materially from those in the forward-looking statements. Factors that may cause such differences are discussed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2004, and other filings made with the Securities and Exchange Commission. In particular, results obtained in the Phase II study may not be

predictive of results to be obtained in the additional evaluations that would be necessary to demonstrate ularitide to be safe and effective in the treatment of decompensated congestive heart failure, nor can there be assurance that PDL will initiate subsequent clinical trials of ularitide.

Protein Design Labs and the PDL logo are registered U.S. trademarks of Protein Design Labs, Inc.

**Protein Design Labs, Inc.**

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