

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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):

March 23, 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))

Item 8.01 Other Events.

On March 23, 2005, Protein Design Labs, Inc., a Delaware corporation ("PDL") announced that it has discussed with the U.S. Food and Drug Administration ("FDA") the future development pathway for PDL's Nuvion® (visilizumab) humanized anti-CD3 antibody being developed for the treatment of intravenous steroid-refractory ulcerative colitis. A copy of the press release announcing PDL's discussion with the FDA about Nuvion is attached hereto as Exhibit 99.1 and is incorporated herein by this reference.

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 March 23, 2005.

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: March 25, 2005

PROTEIN DESIGN LABS, INC.

By: /s/ Sergio Garcia-Rodriguez
Sergio Garcia-Rodriguez
Vice President, Legal, General Counsel
and Assistant Secretary



For Immediate Release

Contact:

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**PROTEIN DESIGN LABS REPORTS ON NUVION® (VISILIZUMAB) END OF PHASE I
MEETING HELD WITH THE FDA**

PDL plans Phase II / III clinical trial in IV steroid-refractory ulcerative colitis

Fremont, Calif., March 23, 2005 — Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI), today said that it has discussed with the U.S. Food and Drug Administration (FDA) the future development pathway for PDL's Nuvion® (visilizumab) humanized anti-CD3 antibody being developed for the treatment of intravenous steroid-refractory ulcerative colitis.

Steven Benner, M.D., Senior Vice President and Chief Medical Officer, PDL, said, "At an end-of-Phase I meeting, we explored with the agency various potential development paths. As a result of these discussions, we are now considering a plan to conduct two pivotal clinical trials and a retreatment study of Nuvion in the setting of intravenous steroid-refractory ulcerative colitis. The first pivotal study will be a Phase II / III clinical trial, instead of a Phase III trial, and is expected to begin this year. Assuming certain protocol-defined criteria are met at the time of the interim analysis, the second pivotal trial would be initiated. We anticipate initiating the retreatment study at the time of the Phase II / III study. We believe that this approach of moving next to a Phase II / III clinical trial strikes an appropriate balance between time of development and development risk.

"Based on this development pathway, we will not pursue a Special Protocol Assessment; however, the proposed protocols will be reviewed in detail by the FDA," Dr. Benner added. "Over the next weeks, we expect to more fully refine the development plan and its impact on the overall development timeline, but anticipate that the time to complete the proposed registrational studies will be longer than we have previously hoped. Nuvion continues to be our highest priority program and we are committed to making this novel therapy available to patients with intravenous steroid-refractory ulcerative colitis. We expect to provide a further development update by the end of May 2005."

Ongoing Phase I / II Clinical Trial in IV Steroid-Refractory Ulcerative Colitis

PDL is currently conducting a Phase I / II clinical trial of visilizumab in patients with IV steroid-refractory ulcerative colitis. The Phase I portion of the trial was designed to explore four dose levels at 5, 7.5, 10 or 12.5 micrograms/kg administered intravenously on days 1 and 2 as a bolus injection. Up to 20 patients per dose cohort will be enrolled, with up to an additional 40 patients to be enrolled in the Phase II portion of the trial, for an expected total of approximately 120 patients treated. PDL is now

enrolling visilizumab-naïve patients in the Phase II component of the study at the 5 micrograms/kg dose level, administered on days 1 and 2.

In a completed, 32-patient Phase I study of two dose cohorts that was reported in May 2004, a strong signal of activity was observed in the first dose cohort given at 15 micrograms/kg on days 1 and 2, in which all eight patients achieved remission. A continued strong signal of activity subsequently was observed in the second dose cohort given at 10 micrograms/kg administered on days 1 and 2. At the 10 micrograms/kg dose level, 19 of 24 patients responded to treatment and of these, 13 achieved remission. "Visilizumab has demonstrated activity at all dose levels tested to date," Dr. Benner commented.

In each of the studies reported to date, the most common adverse events have been associated with the cytokine release syndrome, which generally consists of flu-like symptoms typically characterized by fatigue, nausea, chills and headache and a transient rise in liver enzymes. The flu-like symptoms were generally transient in nature, were seen less frequently following the second day of treatment and typically resolved within 24 hours following the second treatment. In addition, visilizumab induces a transient decline in T cells and frequently an associated transient rise in Epstein-Barr virus (EBV) titers. The decline in T cells could result in an increased incidence of infections, although this has not been observed thus far in the clinical trials in patients with IV steroid-refractory ulcerative colitis.

PDL currently expects to present additional clinical information regarding visilizumab at the Digestive Disease Week meeting to be held in Chicago, May 14-19.

In September 2004, PDL announced that the FDA had granted Fast Track status to the investigation of visilizumab in patients with IV steroid-refractory ulcerative colitis. Designation as a Fast Track product indicates that the FDA will facilitate the development and expedite the review of a new drug that is intended to treat a serious or life-threatening condition, and that demonstrates the potential to address an unmet medical need. However, Fast Track designation does not mean that the FDA will expedite approval of any application for the product or guarantee approval of the product.

About Visilizumab

Visilizumab is a humanized non-FcR binding monoclonal antibody directed at the CD3 antigen on T cells. Increasing evidence implicates T lymphocytes as the primary immune cells mediating the induction and progression of inflammatory bowel disease. While the mechanism of action of visilizumab in ulcerative colitis is still being characterized in ongoing studies, early research has demonstrated that visilizumab induces selective apoptosis of activated, but not resting human T cells in *in vitro* cell biology experiments. If these observations are established *in vivo*, it may provide an explanation to the rapid therapeutic benefit in ulcerative colitis. Research studies continue on visilizumab’s effects on the resting T cell populations that appear not susceptible to *in vitro* apoptosis.

About PDL

Protein Design Labs is a leader in the development of humanized antibodies to prevent or treat various disease conditions. PDL currently has antibodies under development for autoimmune and inflammatory conditions, asthma and cancer. PDL holds fundamental patents for its antibody humanization technology. Further information on PDL is available at www.pdl.com.

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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 PDL’s Annual Report on Form 10-K for the year ended December 31, 2004, and in other filings made with the Securities and Exchange Commission. In particular, there can be no assurance that *Nuvion* will prove safe and efficacious in clinical studies for the treatment of ulcerative colitis, or that PDL will undertake a Phase II / III or Phase III clinical studies of Nuvion for the potential treatment of steroid-refractory ulcerative colitis, or that the FDA will ultimately accept the Company’s development program as approvable or that such program will ultimately lead to regulatory approval.

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