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):
January 12, 2005

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-19756**	**94-3023969**
(State or other jurisdiction of incorporation)	*(Commission File No.)*	*(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On January 12, 2005, the Company issued a press release (the "Press Release") updating its financial guidance for the full year 2004 from that provided on November 1, 2004. The Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Use of Non-GAAP Financial Information

To supplement the information that is presented in accordance with U.S. generally accepted accounting principles ("GAAP"), in our historical information for the period presented as well as our forward-looking guidance in the press release and conference call, we provide certain non-GAAP financial measures that exclude from the directly comparable GAAP measures certain non-cash charges, including charges related to acquisitions such as acquired in-process research and development and amortization of workforce as well as stock compensation expense. We believe that these non-GAAP measures enhance an investor's overall understanding of our financial performance and future prospects by reconciling more closely to the actual cash expenses of the Company in its operations as well as excluding expenses that in management's view are unrelated to our core operations, the inclusion of which may make it more difficult for investors and financial analysts reporting on the Company to compare our results from period to period. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with GAAP, and non-GAAP financial measures as reported by the Company may not be comparable to similarly titled items reported by other companies.

Item 7.01 Regulation FD Disclosure.

The Press Release also provides updates of the status of clinical development programs and partnering objectives. The Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release, issued by Protein Design Labs, Inc. on January 12, 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: January 12, 2005

PROTEIN DESIGN LABS, INC.

By: /s/ SERGIO GARCIA-RODRIGUEZ

Sergio Garcia-Rodriguez
Vice President, Legal, General Counsel and Assistant Secretary

Exhibit 99.1

www.pdl.com

For Immediate Release

Contact:

James R. Goff
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PDL UPDATES STATUS OF CLINICAL DEVELOPMENT PROGRAMS AND PARTNERING OBJECTIVES

Initiates Phase II clinical trial of M200 (volociximab) in renal cell cancer; updates 2004 financial guidance; sees potential acquisition or in-license of marketed drug in 2005 to accelerate path to positive cash flow

Fremont, Calif., January 12, 2005 – Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today provided an update on the status of its principal drug development programs, as well as an overview of its 2005 corporate partnering objectives.

"We are pleased to report that we have begun a Phase II study of M200, our novel anti-angiogenesis agent, in patients with renal cell carcinoma," said Steven Benner, M.D., Senior Vice President and Chief Medical Officer, PDL. "Our highest development priority remains *Nuvion* for intravenous steroid-refractory ulcerative colitis. We currently expect to conduct an end-of-Phase I meeting with the FDA regarding *Nuvion* at the end of the current quarter or early in the second quarter, at which time we expect to discuss with the agency the future development pathway for this promising antibody. Having received Fast Track status in September 2004, we continue to believe that visilizumab represents a major potential advance in the treatment of I.V. steroid-refractory ulcerative colitis.

"We also continue to be excited by the promise of daclizumab in asthma and certain other diseases," Dr. Benner added. "Following our discussions with the FDA, we altered our development plan to include both a Phase I single-dose healthy volunteer study, followed by a Phase I multiple-dose, healthy volunteer study. We expect to initiate the Phase I single-dose study in the current quarter and the Phase I multiple-dose study in the second half of this year. These studies are intended to gain additional experience with the PDL-manufactured, subcutaneous formulation of daclizumab, as distinct from the current intravenous formulation of marketed daclizumab which is manufactured by our partner, Roche."

***Nuvion* Antibody Product (visilizumab, humanized anti-CD3).** PDL is currently conducting a Phase I/II dose-ranging clinical trial in patients with ulcerative colitis who have not responded to treatment with intravenous (I.V.) steroids. The trial is designed to evaluate four dose levels escalating from 5 micrograms/kg to 12.5 micrograms/kg given I.V. on days 1 and 2 as a bolus injection. PDL expects to enroll up to 20 patients per dose cohort, or a total of approximately 80 patients in the Phase I portion of the study. A total of 84 patients have been enrolled to date.

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Following the Phase I portion, PDL will select the optimal clinical dose, and will subsequently treat up to an additional 40 visilizumab-naïve patients at the optimal clinical dose in the Phase II portion of the study. The Phase II portion is expected to begin in the first quarter of 2005. PDL has submitted an abstract of results from this ongoing clinical trial for possible presentation at the Digestive Disease Week meeting, to be held in Chicago in early May 2005.

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 I.V. 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.

Specific milestones for *Nuvion* in 2005 include preparation for and meeting with the FDA in an end-of-Phase I meeting targeted for the end of the first quarter, or early in the second quarter. If the FDA agrees with PDL's plan to move to pivotal trials as the appropriate next step, this meeting would be followed by efforts to procure a Special Protocol Assessment for the two Phase III trials, which trials PDL anticipates could be initiated by year end. In addition, PDL plans to begin, in the first quarter, at least one of two small studies in severe Crohn's disease with *Nuvion* and to begin a pediatric ulcerative colitis study in the second half of 2005. However, the company continues to focus on the induction regimen studies in steroid-refractory ulcerative colitis as the basis for PDL's initial registration approach.

Daclizumab (humanized anti-CD25). In September 2004, PDL and Roche announced a worldwide agreement to co-develop and commercialize daclizumab for asthma and related respiratory diseases. PDL now expects that the next trial of daclizumab in asthma will be a single-dose, Phase I clinical trial intended to gather additional experience with the PDL-manufactured subcutaneous formulation of daclizumab in healthy volunteers. This single-dose subcutaneous study should begin in the first quarter of this year.

"Because we now plan to conduct a single-dose trial followed by a multiple-dose Phase I study, we anticipate that the subsequent Phase IIb clinical trial in moderate-to-severe persistent asthma should begin in the first quarter of 2006," Dr. Benner said.

In March 2004, PDL reported positive results from the initial clinical study of intravenous daclizumab in patients with chronic, persistent asthma whose disease is not well controlled with high doses of inhaled corticosteroids. There were statistically significant treatment differences ($p=0.05$) observed for the primary endpoint, percent change in FEV_1 from baseline to 12 weeks (day 84). Secondary clinical endpoints also supported these findings. Treatment with daclizumab was generally well tolerated.

Preparatory work for a PDL study of daclizumab in multiple sclerosis (MS) remains on track, and the company currently plans to initiate a Phase II study in MS at the end of the current quarter.

"ZENAPAX® (daclizumab) is marketed by Roche for the prophylaxis of acute organ rejection in patients receiving renal transplants," Dr. Benner commented. "We see additional potential for daclizumab in solid organ transplantation, and are looking at various options for that indication."

M200 (volociximab, anti-alpha5beta1 integrin). M200 is a novel anti-angiogenic antibody that targets the endothelium of tumor neovasculature. Earlier this month, PDL began a Phase II clinical trial in patients with renal cell carcinoma using M200 as a single agent, the first in a series of up to five open-label, Phase II trials of M200 in selected solid tumors. The trials currently contemplated include three combination studies with chemotherapy, as well as single-agent use. The planned combination studies would include M200 plus standard of care treatment in each of melanoma, pancreatic cancer and non-small cell lung cancer (NSCLC). The single- agent studies include M200 in renal cell cancer, now underway, while a planned study in melanoma could be initiated later in 2005.

In September 2004, PDL presented interim clinical data from a Phase I dose-escalation study of M200 for the treatment of refractory solid tumors. Tumor types included colorectal, melanoma, hepatic, pancreatic and non-small cell lung cancers. Patients were enrolled as follows: one patient at 0.5 mg/kg, 2 patients at 1 mg/kg, 3 patients at 2.5 mg/kg, 3 patients at 5.0 mg/kg and 6 patients at 10 mg/kg. Each patient received 5 doses of M200 on study days 1, 15, 22, 29 and 36. The study data showed that adverse events were generally mild to moderate in intensity and included fatigue, nausea, constipation, headache and anorexia. There were no severe or serious adverse events that were dose limiting or considered by investigators to be related to M200.

In addition, as part of the September 2004 interim analysis, 10 of 15 evaluable patients had stable disease as their best response, and five of six patients treated at the 10 mg/kg dose level, achieved stable disease. Four patients with stable disease after 5 doses of M200 in the Phase I study continued treatment with M200 in a Phase I extension study.

Since September, PDL has completed enrollment into the Phase I portion of the trial with a total of 21 patients treated. Of interest, a partial response has been observed in one patient with renal cell cancer during treatment in the extension study.

PDL does not currently anticipate major conference or scientific presentations related to M200 in 2005, given the fact that the new Phase II studies are being initiated, but are not expected to be completed, in calendar 2005. PDL anticipates that abstracts for some of these studies should be available for submission prior to the 2006 ASCO meeting.

Financial and Business Update. PDL updated its financial guidance for the full year 2004, from that provided on November 1, 2004. The company now anticipates that its non-GAAP net loss for 2004 will be approximately $0.01 to $0.03 per basic and diluted share less than its previously estimated net loss, and therefore is now expected to be in the range of $0.50 to $0.55 per basic and diluted share. The GAAP net loss for the full

year 2004 is now expected to be in the range of $0.55 to $0.60 per basic and diluted share. Non-GAAP results do not include expenses resulting from amortization of intangible assets, restructuring charges and stock-based compensation. The company expects to provide a review of 2004 as part of its year-end conference call to be scheduled in the second half of February 2005, and will also provide 2005 financial guidance on that call.

In advance of the call, however, the company has provided a brief outline of partnering objectives and business goals for 2005. These include (i) entering into a daclizumab global alliance, for development and commercialization in multiple sclerosis; (ii) establishing a corporate partnership around further development and commercialization of *HuZAF*, PDL's anti-gamma interferon antibody for potential use in Crohn's disease; (iii) completing 1 to 2 patent license or humanization agreements; (iv) meeting commissioning and validation steps necessary for 2006 clinical supply production at its Brooklyn Park, Minn. manufacturing plant; and (v) potentially in-licensing or acquiring a hospital-marketed novel therapeutic agent.

PDL's Chief Executive Officer, Mark McDade, commented, "We believe that these aggressive aims for 2005 clearly demonstrate the PDL team's commitment to accelerate our path to a positive cash flow. Forging product partnerships can enable additional resources for optimized product development while potentially reducing PDL's overall burn. And the acquisition or in-license of a currently marketed drug, synergistic with our therapeutic areas or our hospital-focused future plans for *Nuvion* and ZENAPAX, could also accelerate our timeline to get to cash flow breakeven and beyond. If we accomplish these partnering-related aims, 2005 should be an exciting and truly transforming year for PDL."

* * * * *

The foregoing contains forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those, express or implied, in the forward-looking statements. In particular, there can be no assurance that results from completed and ongoing clinical studies, described above, will be successful or completed or initiated on the anticipated schedules or that partnering objectives will be achieved during the year, or at all. Financial results for 2004 are unpredictable and may fluctuate from quarter to quarter. PDL expenses, in principal part, depend on the total headcount of the organization and the timing of expenses. PDL revenues depend on the success and timing of sales of our licensees and partners, including in particular the continued successful launch of Avastin antibody product by Genentech, as well as the seasonality of sales of Synagis from MedImmune, Inc. In addition, quarterly revenues may be impacted by our ability to maintain and increase our revenues from licensing, which revenues depend on third parties entering into new patent licensing arrangements, exercising rights under existing patent rights agreements, paying royalties under existing patent licenses and the timing of the recognition of revenues under any new and existing agreements. Our revenues and expenses would also be affected by the continuation of our asthma collaboration with Roche, new collaborations, material patent licensing arrangements or other strategic transactions. Partnering may be impacted by competitive forces, or the lack of PDL's existing commercial infrastructure, so there can be no assurance that the out-licensing, in-licensing or potential product acquisitions will occur during 2005, or at all, which could impact our timeline to positive cash flow.

Other factors that may cause our actual results to differ materially from those, express or implied, in the forward-looking statements in this press release are discussed in our Annual Report on Form 10-K for the year ended December 31, 2003, in our quarterly report on Form 10-Q for the period ended September 30, 2004, and in other filings with the Securities and Exchange Commission.

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.