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):
February 1, 2000

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u>

(State of Other Jurisdiction of Incorporation)

34801 Campus Drive

Fremont, California, 94555

(Address of principal executive offices including zip code)

<u>(510) 574-1400</u>

(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Item 5. Other Matters

On February 1, 2000, Protein Design Labs, Inc. (the "Company") issued a press release announcing preliminary financial results for the quarter and year ended December 31, 1999, and providing and update on product and business development.

On February 1, 2000, the Company also issued a press release announcing the Company's intention to make a private offering of \$100 million of Convertible Subordinated Notes, due 2007, with an option to issue an additional \$25 million of notes.

On February 8, 2000, the Company issued a press release announcing that the Company was delaying the pricing of its private offering of Convertible Subordinated Notes in order to provide time to complete quality control testing of a new lot of an antibody product required for continuation of one of its clinical trials.

On February 10, 2000, the Company issued a press release announcing that the Company had been advised that an independent regulatory consultant had approved the report of additional quality tests for the lot of antibody product mentioned above, and that the product had been released for use.

On February 10, 2000, the Company also issued a press release announcing the private placement of \$125 million principal amount of 5.5% Convertible Subordinated Notes due 2007, and the granting to the initial purchasers an option to purchase up to an additional \$25 million in principal amount of notes.

The foregoing changes are discussed in greater detail in the Company's press releases, copies of which are attached hereto as Exhibits 1-5.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

<u>0-19756</u> <u>94-3023969</u>

(Commission File Number)

Date: February 14, 2000

PROTEIN DESIGN LABS, INC. By: /s/ DOUGLAS O. EBERSOLE

EXHIBIT INDEX

Douglas O. Ebersole, Senior Vice President, Legal and Licensing

(IRS Employer Identification Number)

Exhibit 1

PROTEIN DESIGN LABS ANNOUNCES PRELIMINARY FINANCIAL RESULTS AND UPDATE ON PRODUCT AND BUSINESS DEVELOPMENT

Fremont, CA, February 1, 2000 Protein Design Labs, Inc. (PDL, the Company) (Nasdaq: PDLI) today released certain preliminary financial results for the quarter and year ended December 31, 1999 and provided an update on product and business development.

PDL estimated that it would have revenues of approximately \$8.1 million and a net loss of approximately \$5.9 million (approximately \$0.32 per basic and diluted share) for the three months ended December 31, 1999. These results compare with revenues of \$6.4 million and a net loss of \$5.3 million (\$0.28 per basic and diluted share) in the 1998 fourth quarter. Revenues in the 1999 fourth quarter included royalty revenues from sales of three products licensed under PDL's antibody humanization patents: Synagis® (palivizumab) from MedImmune, Inc., Herceptin® (trastuzumab) from Genentech, Inc., and Zenapax® (daclizumab) from Hoffmann-La Roche Inc. (Roche). As previously announced, royalty revenue from sales of Synagis was reduced by 50% as a result of a credit for a milestone payment by MedImmune in the third quarter of 1999. Other components of revenue included a \$3.0 million noncreditable, non-refundable up-front fee for a patent rights agreement with Celltech Chiroscience plc (Celltech), sponsored research and development funding and interest income.

Total costs and expenses in the 1999 fourth quarter are expected to be approximately \$14.0 million, compared with \$11.6 million in the fourth quarter of 1998. Costs and expenses included a payment to Celltech under the above mentioned patent rights agreement and a milestone payment to Scil Biomedicals GmbH (formerly BioNet Pharma GmbH) for the initiation of a Phase IIa clinical trial with the SMART Anti-L-Selectin Antibody.

PDL expects to report revenues of approximately \$35.8 million and a net loss of approximately \$10.3 million (approximately \$0.55 per basic and diluted share) for the year ended December 31, 1999. These results compare with revenues of \$30.8 million and a net loss of \$9.5 million (\$0.51 per basic and diluted share) in 1998. Total costs and expenses in 1999 are expected to be approximately \$46.1 million, compared with \$40.3 million in 1998.

"It is important to emphasize that the financial information we are providing today is unaudited, preliminary and subject to change," said

Robert L. Kirkman, M.D., Vice President, Business Development and Corporate Communications. "Audited numbers may vary from these preliminary estimates for various reasons, such as adjustments to timing of revenue or expense recognition. We anticipate reporting audited financial results for 1999 during the week of February 28."

PDL also provided an update on product and business development:

- -- Zenapax: In October 1999, PDL reacquired certain development and marketing rights from Roche for potential uses of Zenapax in treating autoimmune diseases. The companies will share revenue from net sales, if any, of Zenapax for autoimmune disease. Zenapax is currently in clinical testing for the treatment of psoriasis and uveitis, both autoimmune diseases. A Phase II trial of Zenapax for the treatment of psoriasis has recently been initiated. PDL plans additional Phase II trials in psoriasis, and plans to begin a Phase I trial in multiple sclerosis.
- -- SMART™ M195 Antibody: In November 1999, PDL announced the initiation of an international multicenter Phase III trial using the SMART M195 Antibody in patients with refractory or first-relapsed acute myelogenous leukemia. The trial will compare the antibody plus standard chemotherapy with chemotherapy alone. The trial includes an interim analysis of the first sixty patients entered.
- -- SMART Anti-CD3 Antibody: PDL is developing the SMART Anti-CD3 Antibody for potential indications in transplantation and autoimmune diseases. PDL has completed Phase I and Phase I/II trials in kidney transplant patients, and recently initiated a Phase II trial for the prevention of rejection in kidney transplant recipients. Based upon early results from this trial, the Company requested the U.S. Food and Drug Administration (FDA) to approve a modification in the dosing regimen for this Phase II trial. After reviewing this request, the FDA asked the Company to place U.S. clinical trials of the antibody in kidney transplantation on clinical hold and to provide the agency with additional data on the antibody. The Company is working with the FDA to resolve this matter as quickly as possible. Importantly, the ongoing U.S. Phase I/II clinical trials of the SMART Anti-CD3 Antibody in psoriasis and graft versus host disease are continuing to accrue patients. The Company expects to initiate a previously planned Phase II trial for the treatment of acute rejection in kidney transplant patients in Europe shortly. The ethics committees in the U.K. and Germany have approved the study and drug has been shipped to the first site. A Phase I trial for the treatment of T cell malignancies is also expected to begin shortly.
- -- SMART Anti-L-Selectin Antibody: Under the auspices of PDL partner Scil Biomedicals, a Phase IIa clinical trial was begun in November 1999 to evaluate the SMART Anti-L-Selectin Antibody in trauma patients.
- -- SMART 1D10 Antibody: At the American Society of Hematology meeting in December 1999, preliminary data from several patients treated in a Phase I trial of this antibody, which is being developed for the treatment of non-Hodgkin's lymphoma, were presented. The data indicated that the antibody was well-tolerated at the doses administered, and the trial is continuing to enroll patients.
- -- SmithKline Beecham agreement: In September 1999, PDL announced a collaboration with SmithKline Beecham (SB) for two humanized antibodies created by SB which are in clinical development for the potential treatment of asthma. Under the agreements, PDL obtained a license to the humanized anti-IL-4 antibody and granted an exclusive license under its antibody humanization patents to SB for its humanized anti-IL-5 antibody.
- -- Celltech agreement: In January 2000, PDL announced a patent rights agreement with Celltech covering certain intellectual property in the field of humanized monoclonal antibodies. Celltech paid a \$3.0 million up-front fee to PDL for rights to obtain non-exclusive licenses under PDL's antibody humanization patents for up to three Celltech antibodies. PDL paid an up-front fee to Celltech for rights to obtain non-exclusive licenses under a Celltech antibody humanization patent for up to three antibodies.

The foregoing contains forward-looking statements involving risks and uncertainties, including those relating to the expected results to be reported for the recently completed quarter and fiscal year and the plans for product and business development activities. In particular, the preliminary financial information reported may differ from the final results and the Company may be unable to report the audited financial information in the time indicated or in a timely manner. Further, the Company and the FDA may not be able to agree on a plan to remove the clinical hold for the SMART Anti-CD3 Antibody or the Company may be required to conduct additional trials of the SMART Anti-CD3 Antibody in transplantation which will delay its development. The Company may experience failures or delays in other clinical trials. Additional risk factors are described in the Company's filings with the Securities and Exchange Commission on Forms 10-K and 10-Q.

Protein Design Labs, Inc. 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, transplantation and cancer. PDL holds fundamental patents in the U.S., Europe and Japan for its antibody humanization technology. Further information on PDL is available at www.pdl.com.

Protein Design Labs, SMART and the PDL logo are registered U.S. trademarks of Protein Design Labs, Inc. Zenapax is a registered U.S. trademark of Hoffmann-La Roche Inc. Herceptin is a registered U.S. trademark of Genentech, Inc. Synagis is a registered U.S. trademark of MedImmune, Inc.

Exhibit 2

PDL ANNOUNCES PRIVATE OFFERING OF CONVERTIBLE SUBORDINATED NOTES

Fremont, CA, February 1, 2000. Protein Design Labs, Inc. (PDL, the Company) (Nasdaq: PDLI) today announced that it intends to make a private offering, subject to market and other conditions, of \$100 million of Convertible Subordinated Notes, due 2007, with an option to issue an additional \$25 million of notes. The notes would be convertible into PDL common stock, at the option of the holder, at a price to be determined. The offering is expected to close in February, 2000.

The proceeds of the anticipated offering are expected to be used to fund clinical trials, to expand manufacturing capabilities and for working capital and other general corporate purposes.

This announcement is neither an offer to sell nor a solicitation of an offer to buy any of these securities.

The notes and the common stock issuable upon conversion of the notes have not been registered under the Securities Act of 1933, as amended (the Securities Act), or any state securities laws. Unless so registered, the notes and the common stock issuable upon conversion of the notes may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws.

The foregoing contains forward-looking statements involving risks and uncertainties, including but not limited to, the ability of the Company to complete the sale of the notes and the ability of the Company to effectively use the proceeds of the sale for the indicated purposes. In particular, market conditions or factors affecting the Company may prevent the completion of the transaction. In addition, the Company may be unable to develop its products and technologies, may experience failures or delays in preclinical or clinical trials, may not expand its manufacturing capabilities, and may be subject to administrative proceedings or disputes regarding its intellectual property. Additional risk factors are described in PDL's filings with the Securities and Exchange Commission on Forms 10-K and 10-Q.

Protein Design Labs, Inc. develops humanized antibodies to prevent or treat various disease conditions. PDL currently has antibodies under development for autoimmune and inflammatory conditions, transplantation, cancer and other conditions. PDL holds fundamental patents in the U.S., Europe and Japan for its antibody humanization technology. Further information on PDL is available through the Company's website at www.pdl.com.

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

PDL ANNOUNCES DELAY IN PRICING OF OFFERING OF SUBORDINATED CONVERTIBLE NOTES

Fremont, CA, February 8, 2000 - Protein Design Labs, Inc. (PDL) (NASDAQ:PDLI) announced that it is delaying the pricing of its private offering of subordinated convertible notes in order to provide time to complete quality control testing of a new lot of an antibody product required for continuation of one of its clinical trials. Additional quality tests beyond those normally used for lot release were required to ensure the sterility of the product. While PDL believes the tests have been satisfactory, a report of the results must be completed and reviewed by an independent regulatory consultant. PDL expects the report to be accepted and the product to be released for use within the next several days. However, if the consultant were to consider the report not to be acceptable, additional tests or report revisions might be required or the product might need to be remanufactured, which could cause significant delays in conduct of the clinical trial and any sales of the product.

This press release contains forward-looking statements involving risks and uncertainties, including those statements relating to the timing and expected results of the review of additional quality tests. Actual results may vary substantially from the expectations contained in the forward-looking statements as a result of the content of the report, the views of the consultant and the time required to complete the review.

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

Exhibit 4

PDL ANNOUNCES RELEASE OF ANTIBODY PRODUCT LOT

Fremont, CA, February 10, 2000 - Protein Design Labs, Inc. (PDL) (NASDAQ:PDLI) announced it has been advised that an independent regulatory consultant has approved the report of additional quality tests for a lot of antibody product required for continuation of one of PDL's clinical trials, and the product lot has been released for use.

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

Exhibit 5

PDL ANNOUNCES PLACEMENT OF \$125 MILLION IN CONVERTIBLE SUBORDINATED NOTES

Fremont, CA, February 10, 2000. Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) announced today the private placement of \$125 million principal amount of 5.5% Convertible Subordinated Notes due 2007. The offering is expected to close on February 15, 2000. The Company has also granted to the

initial purchasers an option to purchase up to an additional \$25 million in principal amount of notes. The notes are convertible into PDL common stock at an initial conversion price of approximately \$151 per share.

The net proceeds of the offering are expected to be used to fund clinical trials, to expand manufacturing capabilities and for working capital and other general corporate purposes.

This announcement is neither an offer to sell nor a solicitation of an offer to buy any of these securities.

The notes and the common stock issuable upon conversion of the notes have not been registered under the Securities Act of 1933, as amended (the Securities Act), or any state securities laws. Unless so registered, the notes and the common Stock issuable upon conversion of the notes may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws.

The foregoing contains forward-looking statements involving risks and uncertainties, including but not limited to, the ability of the Company to complete the sale of the notes and the ability of the Company to effectively use the proceeds of the sale for the indicated purposes. In particular, market conditions or factors affecting the Company may prevent the completion of the transaction. In addition, the Company may be unable to develop its products and technologies, may experience failures or delays in preclinical or clinical trials, may not expand its manufacturing capabilities, and may be subject to administrative proceedings or disputes regarding its intellectual property. Additional risk factors are described in PDL's filings with the Securities and Exchange Commission on Forms 10-K and 10-Q.

Protein Design Labs, Inc. develops humanized antibodies to prevent or treat various disease conditions. PDL currently has antibodies under development for autoimmune and inflammatory conditions, transplantation, cancer and other conditions. PDL holds fundamental patents in the U.S., Europe and Japan for its antibody humanization technology. Further information on PDL is available through the Company's website at www.pdl.com.

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EXMIDIT NO.	<u>Description</u>
1	Press release dated February 1, 2000.
2	Press release dated February 1, 2000.
3	Press release dated February 8, 2000.
4	Press release dated February 10, 2000.
5	Press release dated February 10, 2000.

Description

Evhibit No.