**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):
**September 16, 2004**

**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):

[_] 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 1.01 Entry into a Material Definitive Agreement.**

On September 14, 2004, Protein Design Labs, Inc. ("PDL") and Roche entered into a worldwide agreement (the "Agreement") to co-develop and commercialize Zenapax(R) (daclizumab) for asthma and related respiratory diseases. Under the terms of the Agreement, PDL will receive a $17.5 million upfront payment as well as up to $187.5 million in development and commercialization milestone payments for successful further development of daclizumab in this indication. Roche and PDL will co-develop daclizumab in asthma pursuant to a worldwide development plan, share development expenses equally in the United States and the European Union, and will co-promote the product in the U.S. PDL will be responsible for manufacturing and will lead development in the U.S. Outside the U.S, Roche will lead development and PDL will receive royalties on net sales of the product.

In 1989, Roche acquired the worldwide rights to daclizumab from PDL. In October 2003, Roche resold to PDL all rights to daclizumab, except with respect to transplantation. PDL has the right, exercisable in 2006 and effective in 2007, to re-acquire the transplantation rights from Roche.

**Item 9.01 Financial Statements and Exhibits.**

**(c) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release in Nutley, N.J. and Fremont, CA, dated September 16, 2004, regarding agreement between Protein Design Labs, Inc. and Roche to jointly develop Zenapax for asthma. |
| 99.2 | Press Release in Basel, Switzerland and Fremont, CA, dated September 16, 2004, regarding agreement between Protein Design Labs, Inc. and Roche to jointly develop Zenapax for asthma. |



**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: September 16, 2004

**PROTEIN DESIGN LABS, INC.**

By: /s/ Sergio Garcia-Rodriguez

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

Sergio Garcia-Rodriguez



**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release in Nutley, N.J. and Fremont, CA, dated September 16, 2004, regarding agreement between Protein Design Labs, Inc. and Roche to jointly develop Zenapax for asthma. |
| 99.2 | Press Release in Basel, Switzerland and Fremont, CA, dated September 16, 2004, regarding agreement between Protein Design Labs, Inc. and Roche to jointly develop Zenapax for asthma. |

**Exhibit 99.1**

# Roche and Protein Design Labs to Jointly Develop Zenapax(R) for Asthma

NUTLEY, N.J. and FREMONT, Calif., Sept. 16 /PRNewswire-FirstCall/ -- Roche and Protein Design Labs (PDL) (Nasdaq: PDLI) today announced a worldwide agreement to co-develop and commercialize Zenapax(R) (daclizumab) for asthma and related respiratory diseases, based on recent positive phase II data in patients with moderate to severe asthma.

Mark McDade, Chief Executive Officer, PDL, said, "The continued development of daclizumab in asthma is among PDL's highest clinical development priorities. With Roche as our ongoing partner in this indication, we believe daclizumab will obtain the resources needed to develop the full potential of this humanized antibody in asthma."

"This new agreement will strengthen our pipeline in asthma, where we are currently in phase II development of a novel oral treatment," said William Burns, Global Head of Roche's Pharmaceuticals Division. "We believe that daclizumab will offer patients a significant improvement over today's current therapy. Our long-standing relationship with PDL continues to grow as we develop daclizumab further."

Under terms of the agreement, PDL will receive a $17.5 million upfront payment as well as up to $187.5 million in development and commercialization milestones for successful further development of daclizumab. Roche and PDL will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the US. Outside the US, PDL will receive royalties on net sales of the product in asthma.

## About the Roche - PDL partnership

In 1989, Roche acquired the worldwide rights to daclizumab, a product that has since gained an important position within Roche's transplantation portfolio. In October 2003, Roche resold to PDL all rights to daclizumab, except in transplantation, until 2007 when PDL will have the option to re-acquire the transplantation rights as well. In 2004, PDL approached Roche with compelling phase II data for daclizumab in asthma, leading to today's announcement for the continued co-development of daclizumab in respiratory disorders by Roche and PDL.

## About Asthma

Asthma is among the most common chronic medical conditions in the United States and worldwide, affecting more than 20 million people in the United States, according to the American Lung Association (ALA) and the American Academy of Allergy, Asthma & Immunology (AAAAI). According to a recent report on the global burden of asthma published by the NIH, WHO and the Global Initiative for Asthma, asthma is one of the most common chronic diseases in the world and it is estimated that around 300 million people in the world currently have asthma. The rate of asthma continues to increase and it is estimated that there may be an additional 100 million persons suffering from asthma by 2025. Asthma accounts for 1 in every 250 deaths worldwide.

## About Zenapax

Zenapax is an immunosuppressive humanized monoclonal antibody or "anti-rejection" drug approved by the FDA in December 1997 to be used in combination with other immunosuppressive drugs (cyclosporine and corticosteroids) to prevent acute organ rejection in kidney transplant patients. The recommended dose of Zenapax is 1.0 mg/kg. Based on clinical trials, the standard course of Zenapax therapy is five doses.

The most frequently reported adverse events associated with Zenapax were constipation, nausea, diarrhea and vomiting. Cellulitis and wound infections occurred more frequently in patients treated with Zenapax versus placebo. Severe hypersensitivity reactions following Zenapax administration have been reported rarely.

Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Zenapax. The physician responsible for Zenapax administration should have complete information requisite for the follow-up of the patient. Zenapax should be administered only by healthcare personnel trained in the administration of the drug who have available adequate laboratory and supportive medical resources.

## About Protein Design Labs

In October 2003, PDL acquired all rights to Zenapax(R), excluding transplantation indications but with the option to gain such indication rights by 2007. PDL retains this right in accordance with the terms of the October 2003 agreement.

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.

## About Roche

Hoffmann-La Roche Inc. (Roche), based in Nutley, N.J., is the U.S. prescription drug unit of the Roche Group, a leading research-based health care enterprise that ranks among the world's leaders in pharmaceuticals and diagnostics. Roche discovers, develops, manufactures and markets numerous important prescription drugs that enhance people's health, well-being and quality of life. Among the company's areas of therapeutic interest are: dermatology; genitourinary disease; infectious diseases, including influenza; inflammation, including arthritis and osteoporosis; metabolic diseases, including obesity and diabetes; neurology; oncology; transplantation; vascular diseases; and virology, including HIV/AIDS and hepatitis C.

For more information on the Roche pharmaceuticals business in the United States, visit the company's web site at: http://www.rocheusa.com .

Webcast scheduled for 8:30 a.m. Eastern time on September 16.

PDL will host a webcast beginning at 8:30 a.m. Eastern time on September 16, 2004, to discuss the joint development and commercialization agreement.

The live webcast will be available through the PDL website: www.pdl.com. Please connect to this website at least 15 minutes prior to the live webcast to allow time for any software download that may be needed to hear the webcast. A replay will be available at www.pdl.com starting approximately one hour after completion of the webcast.

An audio replay will also be available by telephone from approximately 10:30 a.m. Eastern time on September 16, 2004 through 10:30 a.m. Eastern time on September 21, 2004. To access the replay, dial 800-633-8284 from inside the United States and 402-977-9140 from outside the United States; enter conference ID number 21207310.

## Conditions

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, 2003, in its Quarterly Report on Form 10-Q for the three months ended June 30, 2004, and in 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 the antibody to be safe and effective in the treatment of asthma, nor can there be assurance that PDL will initiate subsequent clinical trials in asthma.

NOTE: Protein Design Labs and the PDL logo are registered U.S. trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche.

SOURCE Protein Design Labs, Inc.

-0- 09/16/2004

/CONTACT: James R. Goff, Senior Director, Corporate Communications, of Protein Design Labs, +1-510-574-1421, or jgoff@pdl.com; or Pamela Van Houten, Director, Public Affairs, of Roche, +1-973-562-2231, or pamela.vanhouten@roche.com /

/Web site: http://www.rocheusa.com /

/Web site: http://www.pdl.com /

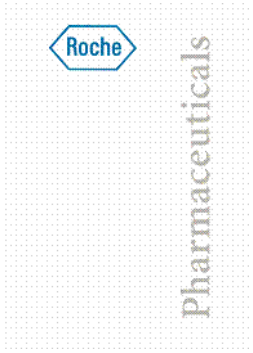
(PDLI)

CO: Protein Design Labs, Inc.; Hoffmann-La Roche Inc.; Roche

ST: California, New Jersey

IN: HEA BIO MTC

SU: JVN PDT CCA




# *Media Release*

Basel, Switzerland and Fremont, CA- 16 September, 2004

## Roche and Protein Design Labs to jointly develop Zenapax for Asthma

Roche and Protein Design Labs (PDL) (NASDAQ: PDLI) today announced a worldwide agreement to co-develop and commercialize Zenapax(R) (daclizumab) for asthma and related respiratory diseases, based on recent positive phase II data in patients with moderate to severe asthma.

Mark McDade, Chief Executive Officer, PDL, said, "The continued development of daclizumab in asthma is among PDL's highest clinical development priorities. With Roche as our ongoing partner in this indication, we believe daclizumab will obtain the resources needed to develop the full potential of this humanized antibody in asthma."

"This new agreement will strengthen our pipeline in asthma, where we are currently in phase II development of a novel oral treatment," said William Burns, Head of Roche's Pharmaceuticals Division. "We believe that daclizumab will offer patients a significant improvement over today's current therapy. Our long-standing relationship with PDL continues to grow as we develop daclizumab further."

Under terms of the agreement, PDL will receive a $17.5 million upfront payment as well as up to $187.5 million in development and commercialization milestones for successful further development of daclizumab. Roche and PDL will globally co-develop daclizumab in asthma, share development expenses and co-promote the product in the US. Outside the US, PDL will receive royalties on net sales of the product in asthma.

***- more -***

**F. Hoffmann-La Roche Ltd** CH-4070 Basel Roche Pharma Partnering Tel.: +41 61 688 9358
http://www.roche.com

**About the Roche - PDL partnership**

In 1989, Roche acquired the worldwide rights to daclizumab, a product that has since gained an important position within Roche's transplantation portfolio. In October 2003, Roche resold to PDL all rights to daclizumab, except in transplantation, until 2007 when PDL will have the option to re-acquire the transplantation rights as well. In 2004, PDL approached Roche with compelling phase II data for daclizumab in asthma, leading to today's announcement for the continued co-development of daclizumab in respiratory disorders by Roche and PDL.

**About Asthma**

Asthma is among the most common chronic medical conditions in the United States and worldwide, affecting more than 20 million people in the United States, according to the American Lung Association (ALA) and the American Academy of Allergy, Asthma & Immunology (AAAAI). According to a recent report on the global burden of asthma published by the NIH, WHO and the Global Initiative for Asthma, asthma is one of the most common chronic diseases in the world and it is estimated that around 300 million people in the world currently have asthma. The rate of asthma continues to increase and it is estimated that there may be an additional 100 million persons suffering from asthma by 2025. Asthma accounts for 1 in every 250 deaths worldwide.

**About Protein Design Labs**

In October 2003, PDL acquired all rights to Zenapax(R), excluding transplantation indications but with the option to gain such indication rights by 2007. PDL retains this right in accordance with the terms of the October 2003 agreement.

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.

**About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is number one in

**F. Hoffmann-La Roche Ltd** CH-4070 Basel Roche Pharma Partnering Tel.: +41 61 688 9358
http://www.roche.com



the global diagnostics market, a leading supplier of pharmaceuticals for cancer and transplantation and a market leader in virology. In 2003 prescription drug sales by the Pharmaceuticals Division totalled 19.8 billion Swiss francs, while the Diagnostics Division posted sales of 7.4 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has alliances and R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

**Webcast scheduled for 8:30 a.m. Eastern time on September 16.**

PDL will host a webcast beginning at 8:30 a.m. Eastern time on September 16, 2004, to discuss the joint development and commercialization agreement.

The live webcast will be available through the PDL website: www.pdl.com. Please connect to this website at least 15 minutes prior to the live webcast to allow time for any software download that may be needed to hear the webcast. A replay will be available at www.pdl.com starting approximately one hour after completion of the webcast.

An audio replay will also be available by telephone from approximately 10:30 a.m. Eastern time on September 16, 2004 through 10:30 a.m. Eastern time on September 21, 2004. To access the replay, dial 800-633-8284 from inside the United States and 402-977-9140 from outside the United States; enter conference ID number 21207310.

Conditions

*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, 2003, in its Quarterly Report on Form 10-Q for the three months ended June 30, 2004, and in 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 the antibody to be safe and effective in the treatment of asthma, nor can there be assurance that PDL will initiate subsequent clinical trials in asthma.*

*Protein Design Labs and the PDL logo are registered U.S. trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche.*



**Contacts:**


| | | |
|---|---|---|
| ***Roche-Europe*** | | ***PDL*** |
| Sabrina Oei | Maria Payne | James R. Goff |
| Pharma Partnering | DeFacto Communications | Senior Director, Corporate Communications |
| Tel: +41 61 688 9358 | Tel: +44 (0) 207 496 3300 | Tel: (510) 574-1421 |
| sabrina.oei@roche.com | | jgoff@pdl.com |


ENDS


| | | | |
|---|---|---|---|
| **F. Hoffmann-La Roche Ltd** | CH-4070 Basel | Roche Pharma Partnering | Tel.: +41 61 688 9358<br>http://www.roche.com |