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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):

**October 28, 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 1.01 Entry into a Material Definitive Agreement.

On October 28, 2005, Protein Design Labs, Inc., a Delaware corporation ("PDL") and Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd (collectively, "Roche") executed an Amended and Restated Co-Development and Commercialization Agreement and a Second Amended and Restated Worldwide Agreement (collectively, the "Agreements"). The Agreements amended the Amended and Restated WORLDWIDE Agreement dated October 1, 2003 and the Co-Development and Commercialization Agreement dated September 14, 2004 between Roche and PDL (the "Prior Agreements").

The Agreements expand the existing relationship between the parties to include the co-development and commercialization of daclizumab for organ transplant patients on longer term, maintenance therapy ("transplant maintenance"). The Agreements provide that PDL will receive a \$10 million upfront payment and may receive up to \$145 million in development and commercialization milestone payments if the development of daclizumab in transplant maintenance is successful. Roche and PDL will share global development costs equally. PDL will have the option to co-promote daclizumab for transplant maintenance in the United States and will share in the profits in the United States, and PDL will receive royalties on net sales of the product in transplant maintenance outside the United States.

The Agreements also provide that PDL will not exercise its option to promote Zenapax for prevention of acute kidney transplant rejection, and PDL is no longer required to make a payment for such right that would otherwise be due in 2007. The Agreements also amended the royalty obligations of Roche with respect to future sales of Zenapax in the existing transplant indication by including a revenue threshold below which royalties are not due. The other provisions of the Prior Agreements were not materially altered by the Agreements.

The press release announcing the transaction and containing a description of certain other terms of the Agreements 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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, issued by Protein Design Labs, Inc. on November 1, 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: November 3, 2005

**PROTEIN DESIGN LABS, INC.**

By: /s/ Glen Y. Sato

**Glen Y. Sato**

**Senior Vice President and  
Chief Financial Officer**



Pharmaceuticals

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**News Release**

**Roche and Protein Design Labs to Jointly Develop Daclizumab in  
Transplant Maintenance Therapy**

**Nutley, N.J. and Fremont, C.A. – November 1, 2005** - Roche and Protein Design Labs, Inc. (PDL) (NASDAQ: PDLI) today announced an expansion to their partnership to co-develop and commercialize daclizumab for organ transplant patients on long-term, maintenance therapy. Roche currently markets daclizumab for induction transplant therapy as Zenapax<sup>®</sup>. Roche and PDL are developing a new subcutaneous daclizumab (daclizumab s.c.) formulation, manufactured by PDL, for use in Phase II clinical trials expected to start in 2006.

Currently, transplant patients are treated with the combination therapy of Roche's CellCept<sup>®</sup> (mycophenolate mofetil) with a calcineurin inhibitor such as cyclosporine and steroids to prevent organ rejection. However, the long-term use of the current calcineurin inhibitors can cause kidney toxicity, diabetes and cardiovascular disorders. Using daclizumab s.c. as maintenance treatment in combination with CellCept may allow for the reduction, and potential elimination, of the more toxic drugs from transplant patient maintenance regimens.

Mark McDade, Chief Executive Officer, PDL, said, "We are enthusiastic about the opportunity to develop daclizumab s.c. with our longstanding partner Roche. Today's agreement

**Hoffmann-La Roche Inc.**

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Public Affairs Department

- more -

builds upon our existing collaboration with Roche in asthma, as we continue to explore development of daclizumab s.c. in other indications."

"Roche and PDL are highly committed to daclizumab, our partnership, and in developing better treatments to improve long-term outcomes for transplant patients," said Peter Hug, Roche's Global Head of Pharma Partnering. "With the potential to use CellCept<sup>®</sup> and daclizumab s.c. as the centerpiece for long-term transplant therapy, we could offer patients a safer, more tolerable option."

Roche and PDL have amended their current agreements to reflect the scope of daclizumab s.c.'s further development. Under the terms of this agreement, PDL will receive a \$10 million upfront payment and may be eligible to receive payments up to \$145 million if certain milestones are satisfied and if the indication is successfully developed. Roche will continue to manufacture and promote Zenapax<sup>®</sup> exclusively on a worldwide basis. Roche and PDL will share equally global development costs, and PDL has the option to co-promote daclizumab s.c. for transplant maintenance in the United States. Outside the United States, PDL will receive royalties on net sales of the product in transplant maintenance. As part of this arrangement, the parties agree that PDL will not exercise its option to promote Zenapax<sup>®</sup> for prevention of acute kidney transplant rejection and PDL is no longer required to make the payment which would otherwise be due in 2007 for such right. PDL and Roche will continue with the co-development of daclizumab s.c. in respiratory disorders, as announced in September 2004.

**About the Roche - PDL partnership**

In 1989, Roche acquired the worldwide rights to daclizumab, a product approved in 1997 as Zenapax<sup>®</sup> for the prevention of renal allograft rejection. In October 2003, Roche returned to

PDL all rights to daclizumab, except in transplantation where PDL retained the option until 2007 to re-acquire development rights. In September 2004, PDL and Roche announced the continued co-development of daclizumab s.c. in respiratory disorders.

**Roche in Transplantation**

Roche is strongly committed to improving the long-term outcomes of transplantation and enhancing the quality of life of transplant recipients. Roche has developed innovative therapies that improve graft and post-transplant health. CellCept is the cornerstone of current immunosuppressant therapies for transplant recipients and is the largest selling branded immunosuppressive in North America. Zenapax<sup>®</sup> prevents acute rejection of the newly transplanted organ. Valcyte<sup>®</sup> (valganciclovir) was developed for the prevention of cytomegalovirus, a dangerous viral infection associated with transplantation. In addition, Roche supports basic research in transplantation with its funding of the independent Roche Organ Transplantation Research Fund (ROTRF), which directly supports innovative research projects attracting new researchers with innovative and novel scientific ideas to meet unmet medical needs in solid organ transplantation.

### About Protein Design Labs

PDL is a biopharmaceutical company focused on the research, development and commercialization of novel therapies for inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several products in the United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. 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. Further information on PDL is available at [www.pdl.com](http://www.pdl.com).

### About Roche – More Than a Century in the U.S. and the World

Founded in 1896 and headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is one of the world's leaders in diagnostics, the leading supplier of pharmaceuticals for cancer, as well as a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on many fronts to improve people's health and quality of life. Roche employs roughly 65,000 people in 150 countries, including approximately 15,000 in the United States. For further information, please visit our worldwide and U.S. website (Global: [www.roche.com](http://www.roche.com) and U.S.: [www.roche.us](http://www.roche.us)).

### Facts About Zenapax, CellCept and Valcyte

**Zenapax** is a humanized monoclonal antibody that blocks interleukin-2 (IL-2) receptors and acts as an immunosuppressant. It is used just before and/or at the time of kidney transplantation in combination with cyclosporine and corticosteroids to prevent early rejection. The recommended dose of Zenapax is 1.0 mg/kg. Based on clinical trials, the standard course of Zenapax therapy is five doses. Zenapax received U.S. Food and Drug Administration (FDA) approval in December 1997.

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.

**CellCept** is an immunosuppressant or anti-rejection drug approved for use in combination with other immunosuppressive drugs (cyclosporine and corticosteroids) for the prevention of rejection in patients receiving kidney, heart and liver transplants.

There are no adequate and well-controlled studies in pregnant women. As CellCept (mycophenolate mofetil) has been shown to have teratogenic effects in animals at subclinical doses on a body surface area basis, it may cause fetal harm when administered to a pregnant woman. CellCept should not be used in pregnant women unless the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should have a negative serum or urine pregnancy test with a sensitivity of at least 50 mIU/mL within one week prior to beginning therapy even where there has been a history of infertility, unless due to hysterectomy.

Women of childbearing potential must use effective contraception before beginning CellCept therapy, during therapy and for six weeks following discontinuation of therapy. Two reliable forms of contraception must be used simultaneously unless abstinence is the chosen method. If pregnancy occurs during treatment, the physician and patient should discuss the desirability of continuing the pregnancy (see complete product information).

Adverse events reported in >30% of renal, cardiac or liver transplant patients receiving CellCept (in combination with cyclosporine and corticosteroids) were pain, fever, headache, asthenia, anemia, leucopenia (patients should be monitored for neutropenia; dosing should be interrupted or the dose reduced if neutropenia develops), thrombocytopenia, leukocytosis, urinary tract infection, hypertension, hypotension, peripheral edema, hypercholesterolemia, hypokalemia, hyperglycemia, creatinine, BUN and cough increased, hypomagnesemia, diarrhea, constipation, nausea, vomiting, respiratory infection, dyspnea, lung disorder, pleural effusion, tremor and insomnia.

Patients receiving immunosuppressant regimens are at increased risk of developing lymphomas and other malignancies, particularly of the skin.

**Warning:** Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

**Valcyte**, the oral pro-drug of Cytovene (ganciclovir), is the most widely prescribed anti-CMV medication in the United States. Valcyte is indicated for the prevention of CMV disease in kidney, kidney-pancreas and heart transplant patients at high risk. Valcyte is not approved for use in liver transplantation.

The efficacy and safety of Valcyte in other solid organ transplants, such as lung transplant, have not been established.

The clinical toxicity of Valcyte, which is metabolized to ganciclovir, includes granulocytopenia, anemia and thrombocytopenia. In animal studies ganciclovir was carcinogenic, teratogenic and caused aspermatogenesis. Valcyte tablets should not be administered if the absolute neutrophil count is less than 500 cells/ $\mu$ L, the platelet count is less than 25,000/ $\mu$ L or the hemoglobin is less than 8 g/dL. Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, bone marrow depression and aplastic anemia have been observed in patients treated with Valcyte tablets (and ganciclovir). Other adverse events reported with a frequency of  $\geq$  5% included diarrhea, tremors, fever, nausea, headache, vomiting, insomnia and allograft rejection.

In liver transplant patients, there was a significantly higher incidence of tissue-invasive CMV disease in the Valcyte-treated group compared with the oral ganciclovir group (see CLINICAL TRIALS in the complete product information).

For full prescribing information on CellCept, Zenapax and Valcyte, please visit: [www.rocheusa.com/products/transplantation.html](http://www.rocheusa.com/products/transplantation.html).

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