

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):

May 2, 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 2.02. Results of Operations and Financial Condition

On May 2, 2005, the Company issued a press release (the "Press Release") announcing the Company's financial results for the fiscal quarter ended March 31, 2005 (the "Results") and held a conference call regarding those Results (the "Conference Call"). The Press Release and the script of the Company's management for the Conference Call are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are 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 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 2, 2005, regarding the first quarter 2005 financial results of Protein Design Labs, Inc.
99.2	Script of the Company's management for the earnings call, held on May 2, 2005, regarding the first quarter 2005 financial results of Protein Design Labs, Inc.

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: May 4, 2005

PROTEIN DESIGN LABS, INC.

By: /s/ Douglas O. Ebersole
Douglas O. Ebersole
Senior Vice President, Legal and Secretary



For Immediate Release

Contact:

James R. Goff
Senior Director,
Corporate Communications
(510) 574-1421
jgoff@pdl.com

**PROTEIN DESIGN LABS ANNOUNCES FIRST QUARTER 2005
FINANCIAL RESULTS**

Fremont, Calif., May 2, 2005 – Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported a net loss of \$83.9 million, or \$0.87 per basic and diluted share, for the three months ended March 31, 2005, compared with a net loss of \$12.6 million, or \$0.13 per basic and diluted share, for the three months ended March 31, 2004. Excluding certain non-cash charges described in more detail below, the non-GAAP net loss for the first quarter of 2005 would have been \$2.7 million, or \$0.03 per basic and diluted share, compared with a non-GAAP net loss of \$12.0 million, or \$0.13 per basic and diluted share in the 2004 first quarter. Results for the period include financial performance for ESP Pharma, Inc. (ESP Pharma) for the brief operating period from March 23, 2005, the closing date of the previously announced acquisition, through the end of the calendar quarter.

Total operating revenues in the first three months of 2005 were \$38.8 million, an increase of 40% over total revenues of \$27.6 million in the first three months of 2004. The largest contributor to this revenue growth was a 51% increase in royalties, which totaled \$33.2 million in the 2005 first quarter, compared with royalty revenues of \$22.0 million in the 2004 first quarter. License and other revenues of \$4.7 million in the first quarter of 2005 decreased from \$5.6 million in the same three months in 2004. In addition, as a result of the ESP Pharma acquisition, PDL recognized net product sales revenues, which totaled \$0.9 million for the last six days of the 2005 first quarter. PDL product revenues for the period reflected net sales of *Cardene*[®] IV for the control of hypertension when oral therapy is neither feasible or desirable; IV *Busulfex*[®], a conditioning agent used in connection with bone marrow transplants; and four off-patent branded products. Sales of *Retavase*[®], a product acquired in connection with the ESP Pharma acquisition, were not recorded in the quarter due to the timing of the product transition to ESP Pharma.

As of March 31, 2005, PDL had cash, cash equivalents, marketable securities and restricted investments totaling approximately \$183.7 million, compared with \$397.1 million at December 31, 2004. The March 31, 2005 balances reflected approximately \$435 million in expenditures in the first quarter of 2005 related to the ESP Pharma and *Retavase* acquisitions, repayment of outstanding indebtedness of ESP Pharma of approximately \$14 million, and planned capital expenditures of approximately \$16.0 million in the quarter, which included approximately \$8.0 million related to planned ongoing construction and validation of PDL's manufacturing plant at Brooklyn Park, Minnesota. PDL received net proceeds of approximately \$242 million from its February 2005 placement of convertible senior notes.

Protein Design Labs, Inc.

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Total costs and expenses were \$123.5 million in the first quarter of 2005, compared with \$41.1 million in the same three months of 2004. Excluding certain non-cash charges, which consisted primarily of an acquired in-process research and development charge of \$79.4 million related to the ESP Pharma acquisition, as well as the amortization of intangible assets associated with the Eos Biotechnology, Inc. and ESP Pharma acquisitions and the re-acquisition of rights to manufacture and market *Zenapax*[®] (daclizumab) in 2003, and stock-based compensation charges, non-GAAP total costs and expenses in the 2005 first quarter would have been \$42.3 million compared to non-GAAP expenses of \$40.5 million for the first quarter of 2004.

Research and development expenses increased slightly to \$35.3 million in the 2005 first quarter, compared with \$33.0 million in the same three months of 2004. The increase in research and development expenses reflected additional headcount and associated costs required to pursue research and clinical development programs, contract manufacturing and direct scale-up and manufacturing expense, and increased facility and equipment-related costs. Selling, general and administrative expenses of \$7.7 million were essentially unchanged in the first quarter of 2005 compared to the first quarter of 2004.

Reconciliations of PDL's GAAP results to non-GAAP results are included in the financial results tables accompanying this release.

Recent Corporate Developments

On March 24, 2005, PDL announced that it had completed its acquisition of ESP Pharma, a privately held, hospital-focused pharmaceutical company. ESP Pharma was founded in April 2002 around the acquisition of several therapeutics from Wyeth, including ESP Pharma's leading product, *Cardene* IV.

Under the terms of the ESP Pharma acquisition agreement, all shares of ESP Pharma common and preferred stock were exchanged for 9,853,770 shares of PDL common stock and \$325 million in cash. PDL also completed, through the purchase of ESP Pharma, the acquisition of certain product rights and assets relating to *Retavase* (reteplase) from Centocor, Inc., a biopharmaceutical operating company of Johnson & Johnson. Centocor received \$110 million for the rights to manufacture, develop, market and distribute *Retavase* in the United States and Canada. Additional milestone payments of up to \$45 million will be made if additional conditions relating to the ongoing clinical trials and manufacturing arrangements are satisfied. The total purchase price for ESP Pharma and *Retavase* was approximately \$582 million.

2005 Forward-looking Guidance

The following statements are based on expectations as of May 2, 2005. These statements are forward-looking, and actual results may differ materially. Except for those assumptions and as expressly set forth below, these statements do not include the potential impact of new collaborations, material licensing arrangements or other strategic transactions.

We are updating our guidance from that previously provided on March 14 with respect to our projected GAAP results, in particular as they were expected to affect

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operating expenses. Specifically, our GAAP adjustments reflect (a) elimination of estimated stock compensation expenses of \$10 to \$15 million as a result of recent changes in the U.S. Securities and Exchange Commission position on the timing of mandatory stock option expense reporting which we do not plan to adopt until January 1, 2006; (b) adjustment to the estimated amount of acquired in-process research and development expenses related to the purchase of ESP Pharma and *Retavase* which we have decreased to \$79.4 million from approximately \$88 million; and (c) adjustment of the amortization of intangibles related to the acquisitions of Eos, ESP Pharma, *Retavase* and to our February 2005 convertible notes offering to \$39 million from approximately \$31 million. Our 2005 projected non-GAAP results do not include the foregoing expenses required under GAAP.

We are also updating our guidance from that previously provided on March 14 with respect to our projected non-GAAP results. We are not revising our previously provided guidance on total revenues for 2005. PDL anticipates that our total revenues will be in the range of approximately \$250 to \$260 million. Royalty revenues are expected to be in the range of approximately \$112 to \$115 million, and license and other revenues are anticipated to be approximately \$30 million, an increase from the previously estimated \$20 to \$25 million. Royalty revenue estimates do not include further royalties in 2005 based on sales of *Tysabri*[®] antibody product from Biogen Idec and Elan, which is licensed under PDL's humanization patents but was withdrawn from the market on February 28, 2005, and we have not increased our estimated royalties based on recently announced positive results for Genentech's *Herceptin*[®] or *Avastin*[™] antibody products. Consistent with our previous guidance, PDL currently believes that royalty revenues for each year from 2006 through 2008 should grow approximately 25% per year.

On a non-GAAP basis, net product sales for *Cardene*[®] IV, *Retavase*[®] and IV *Busulfex*[®] are expected to total approximately \$93 to \$95 million for the approximately nine-month period of sales following the close of the acquisition of ESP Pharma. Additionally, PDL anticipates compound annual growth rates of approximately 25% for net product sales of this group of three marketed products for each year from 2006 through 2008. Also for this group of products, PDL currently anticipates gross margins of at least 80% over the 2005 through 2008 period. We are reducing our estimates for net product sales of off-patent products from \$25 million to a range of \$16 to \$20 million.

On a non-GAAP basis, during 2005 we anticipate research and development expenses in the range of \$181 to \$183 million, a reduction from previously estimated \$184 to \$186 million. We continue to expect to spend approximately \$100 million to advance our clinical development programs for *Nuvion*[®], daclizumab and M200. We continue to anticipate sales and marketing expenses in the range of \$42 to \$44 million resulting primarily from the ESP Pharma acquisition. Finally, we anticipate general and administrative expenses for the full year 2005 in the range of \$33 to \$36 million, an increase from \$31 to \$33 million.

In addition, we expect interest income of approximately \$7 million and interest expense of approximately \$8 million.

Overall, for the full year 2005 we anticipate a GAAP net loss in the range of approximately \$1.30 to \$1.37 per basic and diluted share, and a non-GAAP net loss in the range of approximately \$0.17 to \$0.25 per basic and diluted share.

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PDL now estimates that its year-end cash balances will be approximately \$180 million, a change from the prior estimate of \$200 million. This estimate takes into account anticipated capital expenditures of \$38 to \$42 million, approximately half of which represents final validation and completion of our new Brooklyn Park, Minnesota manufacturing facility; cash payments during 2005 of \$325 million and \$110 million for the acquisitions of ESP Pharma and *Retavase*, respectively; the receipt of approximately \$242 million from the February 2005 sale of convertible notes, net of fees and expenses; and the repayment of approximately \$14 million in ESP Pharma-related debt.

By year-end 2005, we estimate that our headcount will be in the range of 900 to 950, split approximately 70% in research and development, 15% in sales and marketing and 15% in general and administrative functions.

Clinical Development Update

***Nuvion*[®] (*visilizumab*, *anti-CD3*).** On March 22, PDL reported that it had discussed with the U.S. Food and Drug Administration (FDA) the future development pathway for *Nuvion* for the treatment of intravenous steroid-refractory ulcerative colitis.

Following these discussions, PDL now expects 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 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. PDL anticipates initiating the retreatment study at the time of the Phase II / III study. The proposed protocols are expected to be reviewed in detail by the FDA. PDL expects to provide a further development update by the end of May 2005.

Additional data from an ongoing Phase I / II study of *Nuvion* will be presented in an oral presentation by Stephan A. Targan, M.D., Director, Cedars-Sinai Division of Gastroenterology and Professor, UCLA School of Medicine, on May 17 beginning at 11:30 a.m. at the Digestive Disease Week meeting to be held in Chicago.

Daclizumab (Zenapax[®], anti-CD25). PDL began in the first quarter of 2005 a single-dose Phase I study of PDL-manufactured daclizumab administered subcutaneously in healthy volunteers. This trial is expected to be followed by a multiple-dose study in healthy volunteers anticipated to be initiated this summer. A Phase II dose range-finding study of subcutaneously administered, PDL-manufactured daclizumab in asthma patients remains on schedule to begin in the first quarter of 2006. PDL also continues to evaluate the opportunity to develop daclizumab further in the setting of solid organ transplantation.

A randomized, placebo-controlled, Phase II study of daclizumab in patients with multiple sclerosis is pending initiation. We anticipate the first patient accrual in the second quarter of 2005. In this study, patients with active relapsing forms of MS will receive subcutaneous daclizumab at one of two dosage levels, or placebo, for six months in addition to their current beta-interferon treatment. The three-arm study is planned to enroll a total of 270 patients.

Ularitide. PDL on April 18 reported positive results from a Phase II clinical study, known as the SIRIUS II trial, of the atrial natriuretic peptide ularitide in patients with decompensated congestive heart failure (DHF).

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The SIRIUS II trial was a randomized, double-blind, placebo-controlled clinical trial conducted at 19 centers in Europe. Primary endpoints in the study were change of pulmonary capillary wedge pressure (PCWP) and change in dyspnea (shortness of breath) score, both at six hours. A total of 221 patients were randomized equally to receive ularitide 7.5, 15, or 30 ng/kg/min given intravenously as a 24-hour infusion, or placebo. In the assessment of the primary endpoints, ularitide significantly reduced PCWP ($p < 0.05$) and improved dyspnea score ($p < 0.05$) in all three dose groups compared to placebo. The main adverse events through day three were dose-dependent decreases in blood pressure compared to placebo. Serum creatinine levels were unchanged during and after ularitide treatment when compared to placebo. The incidence of serious adverse events was similar for all three treatment groups and the placebo group.

The SIRIUS II clinical trial was conducted by CardioPep Pharma GmbH. Through the ESP Pharma acquisition, PDL acquired from CardioPep exclusive rights to conduct all subsequent development and exclusive marketing rights for ularitide for all indications in the United States, Canada, the European Union and Switzerland. To date, the clinical development of ularitide has taken place in Europe. A U.S. Investigational New Drug (IND) application has not yet been filed by CardioPep.

M200 (volociximab, anti-alpha5beta1 integrin antibody). Currently, M200 is being developed as an anti-angiogenic therapy for the treatment of solid tumors in open-label pilot Phase II studies. These trials, each of up to 40 patients, will further assess the tolerability of prolonged administration of M200 and look for evidence of clinical activity. Three clinical trials have now been opened and are enrolling patients. An additional pilot Phase II study is expected to open in the second quarter of 2005. Data from at least two of the initial Phase II studies is expected to be available for presentation during the ASCO meeting in June 2006.

In addition, PDL is planning a pilot Phase II trial of M200 administered intravenously in patients with age-related macular degeneration (AMD), which is expected to begin during the second half of 2005.

Terlipressin. PDL and privately held Orphan Therapeutics, LLC on April 20 reported that the FDA had granted Fast Track status to the development of terlipressin for the treatment of patients with type 1 hepatorenal syndrome (HRS).

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 the product nor does it increase the likelihood of approval of the product.

Through its acquisition of ESP Pharma, PDL acquired from Orphan Therapeutics exclusive marketing, sales and distribution rights for terlipressin in the United States and Canada. Orphan Therapeutics holds the U.S. IND for terlipressin and is conducting a Phase III clinical trial in the United States and Europe. Orphan Therapeutics has obtained Orphan Drug status for this program.

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Webcast Information

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its financial results for the first quarter ended March 31, 2005, the status of its clinical development programs and its forward-looking information and guidance with respect to future results. Financial and statistical information to be discussed in the call will be available on the PDL website immediately prior to the commencement of the call. A link to the conference call webcast will be available through the PDL website: www.pdl.com. Please connect to this website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast. The webcast will be archived at www.pdl.com starting approximately one hour after completion of the webcast. A replay of the conference call will also be available by telephone from approximately 7 p.m. Eastern time on May 2 through 11:59 p.m. Eastern time on May 6, 2005. To access the replay, dial 800-633-8284 from inside the United States and 402-977-9140 from outside the United States and enter conference ID number 21245638.

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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. The forward-looking statements include our expectations regarding financial results and the timing of clinical developments as well as other statements regarding our expectations. Factors that may cause differences between current expectations and actual results include, but are not limited to, the following: The successful integration of ESP Pharma and *Retavase* as part of PDL; fluctuations in sales that may result from our integration of newly acquired operations, from changes in the market due to alternative treatments or other actions by competitors; and variability in expenses particularly on a quarterly basis, due, in principal part, to total headcount of the organization and the timing of expenses. In addition, 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 collaborative arrangements such as our co-development agreement with Roche. Our revenues and expenses would also be affected by new collaborations, material patent licensing arrangements or other strategic transactions.

Further, there can be no assurance that results from completed and ongoing clinical studies, described above, will be successful or that ongoing or planned clinical studies will be completed or initiated on the anticipated schedules. 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 filings with the Securities and Exchange Commission. PDL expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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About PDL

Protein Design Labs is a fully-integrated biopharmaceutical company focused on the development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. 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. PDL markets several biopharmaceutical products in the United States through its wholly-owned subsidiary, ESP Pharma, Inc. Further information on PDL is available at www.pdl.com or by contacting James R. Goff, Senior Director, PDL Corporate Communications, (510) 574-1421 or jgoff@pdl.com.

Protein Design Labs, the PDL logo and Nuvion are registered U.S. trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche. Cardene is a registered trademark of Roche Palo Alto. Retavase and Busulfex are registered trademarks of ESP Pharma, Inc., a wholly-owned subsidiary of PDL. Synagis is a registered U.S. trademark of MedImmune, Inc. Herceptin is a registered U.S. trademark and Avastin is a trademark of Genentech, Inc. Tysabri is a trademark of Elan.

Financial tables attached

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PROTEIN DESIGN LABS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months ended March 31,	
	2005	2004
Revenues:		
Product sales, net	\$ 948	\$ —
Royalties	33,164	22,010
License and other	4,703	5,618
Total revenues	38,815	27,628
Costs and expenses:		
Costs of product sales	1,137	—
Research and development	35,261	33,029
Selling, general and administrative	7,666	8,068
Acquired in-process research and development	79,417	—
Total costs and expenses	123,481	41,097
Operating loss	(84,666)	(13,469)
Interest and other income, net	2,935	2,284
Interest expense	(2,142)	(1,385)
Loss before income taxes	(83,873)	(12,570)
Provision for income taxes	22	48
Net loss	\$ (83,895)	\$ (12,618)
Basic and diluted net loss per share	\$ (0.87)	\$ (0.13)
Shares used in computation of basic and diluted net loss per share	96,754	94,000

CONSOLIDATED BALANCE SHEET DATA (Unaudited)

(In thousands)	March 31, 2005	December 31, 2004*
	(unaudited)	
Cash, cash equivalents, marketable securities, and restricted investments	\$ 183,666	\$ 397,080
Total assets	1,048,777	713,732
Total stockholders' equity	470,543	412,510

*Derived from the December 31, 2004 audited consolidated financial statements.

PROTEIN DESIGN LABS, INC.
NON-GAAP CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

We use non-GAAP amounts that exclude charges related to acquired in-process research and development and certain other non-cash charges, including amortization of intangible assets, and stock-based compensation, as well as other non-recurring charges, such as costs incurred in connection with the extinguishment of our debt and restructuring charges. Management believes 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. Our management uses these non-GAAP financial measures along with the most directly comparable GAAP financial measures in evaluating the company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)

	Three months ended March 31,					
	2005			2004		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Product sales, net	\$ 948		\$ 948	\$ —		\$ —
Royalties	33,164		33,164	22,010		22,010
License and other	4,703		4,703	5,618		5,618
Total revenues	38,815		38,815	27,628		27,628
Costs and expenses:						
Costs of product sales	1,137	\$ (1,060)(1)	77	—		—
Research and development	35,261	(713)(2)	34,548	33,029	\$ (619)(2)	32,410
Selling, general and administrative	7,666	(23)(2)	7,643	8,068	(14)(2)	8,054
Acquired in-process research and development	79,417	(79,417)(3)	—	—		—
Total costs and expenses	123,481	(81,213)	42,268	41,097	(633)	40,464
Operating loss	(84,666)	81,213	(3,453)	(13,469)	633	(12,836)
Interest and other income, net	2,935	—	2,935	2,284	—	2,284
Interest expense	(2,142)	—	(2,142)	(1,385)	—	(1,385)
Loss before income taxes	(83,873)	81,213	(2,660)	(12,570)	633	(11,937)
Provision for income taxes	22	—	22	48	—	48
Net loss	\$ (83,895)	\$ 81,213	\$ (2,682)	\$ (12,618)	\$ 633	\$ (11,985)
Basic and diluted net loss per share	\$ (0.87)		\$ (0.03)	\$ (0.13)		\$ (0.13)
Shares used in computation of basic and diluted net loss per share	96,754		96,754	94,000		94,000

(1) To exclude the ongoing, non-cash amortization of acquired product rights related to the ESP and Retavase acquisitions.

(2) To exclude (i) the ongoing, non-cash amortization of acquired intangible assets, including workforce, related to the Eos acquisition, and core technology, related to the purchase of certain patent rights from Roche and (ii) stock-based compensation charges related to modifications of stock options and stock options issued to non-employees.

(3) To exclude the non-cash charges of acquired in-process research and development, which relate to the ESP acquisition and the purchase of certain technology, that has not achieved technological feasibility.

PROTEIN DESIGN LABS, INC.

CONFERENCE CALL SCRIPT

1Q 05 FINANCIAL RESULTS

May 2, 2005 - 4:30 PM EST

[Operator introduces Jim]

Jim Goff:

Good afternoon everyone, and thank you for joining us today. With me are Mark McDade, Chief Executive Officer; Glen Sato, our Chief Financial Officer; and Dr. Steven Benner, our Chief Medical Officer.

During today's call, we intend to provide an overview of recent clinical and corporate highlights, review PDL's first quarter 2005 results, and update our forward-looking financial guidance for 2005, including effects from the acquisition of ESP Pharma and Retavase.

As we begin, let me remind you that the information we'll cover today contains forward-looking statements regarding our financial performance, clinical milestones and other matters, and our actual results may differ materially from those, express or implied, in the forward-looking statements. Factors that may cause differences between current expectations and actual results are described in our filings with the Securities and Exchange Commission.

I'll now turn the call over to Mark McDade, Chief Executive Officer.

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Mark McDade:

Thank you, Jim. And thanks to all of you for participating in today's first quarter conference call. I'll begin with an overview of a transformational quarter for PDL, Glen will review the financials and forward-looking guidance, and Steve will finish with a clinical update of our now larger pipeline.

This past quarter for PDL has been unquestionably the single most dynamic since we were formed. Importantly, on March 24, we announced that we had closed the acquisition of ESP Pharma, a privately-held, hospital-focused pharmaceutical company. The closing of the ESP Pharma transaction — and the related acquisition of the marketed thrombolytic agent Retavase — have created a fully-integrated biopharmaceutical company with significant potential. In recognition of such a fundamental shift, our Board has just approved the change of our name to PDL Biopharma, Inc. We believe that "PDL Biopharma" retains the recognition many of you have for "PDL", but drops the words "protein" and "design" in favor of adding "biopharma", reflecting the biotech underpinnings that are firmly in place together with our recently-acquired business of selling novel pharmaceuticals in North America. Consequently, we will ask shareholders to approve this new corporate identity at our June 8 annual meeting of stockholders, and hope to fully roll-out this name change by the end of the calendar year. We don't anticipate dropping our ticker, PDLI. I'd also like to express my appreciation for our customers and others outside the company who provided input on the potential name change.

So PDL now has a portfolio of approved therapeutics including three actively marketed products — Cardene IV, Retavase and IV Busulfex — in addition to a 75-person sales force and sales management team, and marketing, medical affairs and sales infrastructure. Because this transaction closed late in the quarter, our numbers include nominal sales for Cardene IV, IV Busulfex and the four off-patent branded products, and

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do not include Retavase sales due to the timing of the product transition to ESP Pharma. As you have likely heard, our aim is to expand sales of each of the key marketed products by capitalizing on synergies, particularly between Cardene IV and Retavase in the acute cardiac care setting, by adding sales-based incentives and, in the longer term, by potentially expanding the label indications for selected products.

The marketed products, together with our rapidly growing royalty revenues and licensing fees, provide a diversified revenue stream and give us a solid financial base to significantly offset the cost of our clinical development and accelerate the path to positive cash flow, which we believe we will achieve starting in the second half of 2006.

Financially, first quarter revenues were the highest ever for PDL, largely due to a 51% increase in royalty revenue compared to the first quarter of 2004, and a 67% increase over royalty revenues in the fourth quarter of last year. As important as this top-line growth, our non-GAAP net loss in the first quarter of 2005, excluding non-cash charges, would have been \$2.7 million, or \$0.03 per basic and diluted share, a figure at the lowest end of any analyst estimate. Excluding non-cash charges, we held expenses relatively constant compared to the same quarter a year ago. We also completed a placement of \$250 million in senior convertible notes essential in financing our acquisitions of both ESP Pharma and Retavase.

In clinical development, the quarter was a busy one. Like many of you, we were disappointed by the delay caused in our registration path for NuVion, but we nevertheless feel that our meeting with the FDA on 21 March was extremely productive in helping to define a clear pivotal path forward. And on the more positive front, we began a single-dose Phase I study using our new subcutaneous daclizumab, three of four planned M200 trials are currently enrolling patients with solid tumors, in April we

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announced positive Phase II results from ularitide, and our partner achieved Fast Track status for terlipressin, our licensed program in a Phase III orphan drug study. Both of these latter programs were acquired as part of our ESP Pharma purchase.

So, we hope your excitement is growing in pace with ours, as we continue to focus on revenue growth, a positive cash flow and building an even deeper and more exciting biotech pipeline – all of which are reflected in our planned new company name – PDL BioPharma.

I'd now like to turn the call over to Glen Sato, our Chief Financial Officer, for a thorough discussion of our numbers for the quarter as well as updated guidance.

Glen Sato:

Thanks, Mark.

This first quarter of 2005 was very strong for PDL and one that we believe demonstrates our commitment to building the company, yet moving forward toward rapidly achieving sustainable positive cash flow from operations in the second half of 2006. We reported a GAAP net loss of \$83.9 million, or 0.87 per basic and diluted share for the first quarter of 2005. But as Mark mentioned, excluding non-cash charges primarily associated with the ESP acquisition, our non-GAAP net loss for the first quarter would have been \$2.7 million, or \$0.03 per basic and diluted share.

Total operating revenues for the first quarter were \$38.8 million, an increase of 40% over total revenues of \$27.6 million for the same period in 2004. This increase in was driven by 51% growth in our humanization-related royalties, which totaled \$33.2 million in the first quarter of 2005, compared with royalty revenues of \$22.0 million in the first quarter of 2004 and \$19.9 million in the fourth quarter of 2004. We did record a

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modest amount of royalties attributable to Tysabri in this first quarter, which, as you know, was taken off of the market in late February.

Although nominal due to our focus at the end of March on closing both the ESP and Retavase acquisitions on March 23, 2005, we recognized net product sales revenues for the final six days of the quarter of \$0.9 million from sales of Cardene IV, IV Busulfex and four off-patent branded products acquired through ESP Pharma. It is important to note that this was a transitional period of net product sales, and that Retavase is not included due to the timing of that product transition, which will result in a full quarter of net product sales for Retavase beginning in the second quarter.

Turning to the expense side, total GAAP costs and expenses reached \$123.5 million in the first quarter compared to \$41.1 million in the similar period of 2004. This included non-cash charges consisting primarily of a \$79.4 million acquired in-process research and development charge related to the ESP acquisition, as well as the amortization of intangible assets associated with the Eos Biotechnology and ESP Pharma acquisitions. Also included are certain amortized costs related to the re-acquisition of rights to manufacture and market daclizumab, which we announced in 2003, and stock-based compensation charges. Without these charges, costs and expenses on a non-GAAP basis would have been \$42.3 million compared to \$40.5 million in the first quarter of 2004. Breaking it down by category when comparing our first quarter results with those of the comparable period in 2004, R&D expenses increased slightly and S,G&A expenses remained virtually unchanged.

As of March 31, 2005, PDL had cash, cash equivalents, marketable securities and restricted investments totaling approximately \$183.7 million, compared with \$397.1 million at December 31, 2004. The March 31, 2005 balances reflected approximately \$435 million in expenditures in the first quarter of 2005 related to the ESP Pharma and

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Retavase acquisitions, repayment of outstanding indebtedness of ESP Pharma of approximately \$14 million, and planned capital expenditures of approximately \$16.0 million in the quarter, which included approximately \$8.0 million related to planned ongoing construction and validation of PDL's manufacturing plant at Brooklyn Park, Minnesota. In addition, our cash position for the quarter included net proceeds of approximately \$242 million from our February 2005 placement of convertible senior notes.

Looking forward, following our initial efforts at integration of ESP Pharma, we have made some revisions to the guidance given on our March 14 year-end call, primarily lowering our overall expected expenses.

Specifically for GAAP reporting, we eliminated \$10 to \$15 million in estimated stock compensation expenses as a result of recent changes in the U.S. SEC position on the timing of mandatory stock option expense reporting, which we now do not plan to adopt until January 1, 2006. We are adjusting the estimated acquired in-process research and development expenses related to the purchases of ESP Pharma and Retavase, which we have decreased to \$79.4 million. And, we have adjusted the amortization of intangibles related to the acquisitions of Eos, ESP Pharma, Retavase and to our February 2005 convertible notes offering to \$39 million from approximately \$31 million. These are non-cash expenses and our 2005 projected non-GAAP results do not include these items reported under GAAP.

Our updated non-GAAP guidance is as follows. Total revenue estimates for 2005 are consistent with our prior guidance of approximately \$250 to \$260 million, as are royalty revenues of \$112 to \$115 million. This assumes no further royalties in 2005 on sales of Tysabri antibody product from Biogen Idec and Elan, which is licensed under PDL's humanization patents but was withdrawn from the market on February 28, 2005,

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and does not include any change to royalties based on recently announced positive results for Genentech's Herceptin or Avastin antibody products. We have increased our license and other revenue to approximately 30 million from the \$20 to \$25 million estimate we previously provided. Total royalty and sales revenues are still expected to grow at 25% per year for 2006 through 2008.

We continue to expect combined product revenues for Cardene IV, Retavase and IV Busulfex to total approximately \$93 to \$95 million for the approximately nine-month period of sales following the close of the acquisition of ESP Pharma. For these same products, we currently anticipate product operating, or gross margins of at least 80% over the 2005 through 2008 period. We are reducing our estimates for net product sales from off-patent products from \$25 million to a range of \$16 to \$20 million, but as you will note from my previous comment, we believe these will be offset by higher licensing and other revenue, so total operating revenue for the year remains within the same overall guidance.

On a non-GAAP basis, based on both timing of expenses related to clinical studies and new efficiencies anticipated during 2005, we are guiding slightly lower for R&D expenses to between \$181 and \$183 million, and slightly higher for G&A to \$33 to \$36 million, with this increase largely due to post-acquisition increased headcount as well as product liability insurance and other expenses associated with the marketing of pharmaceutical products. We maintain our guidance for expected spending of approximately \$100 million to advance our clinical development programs for Nuvion, daclizumab and M200, and sales and marketing expenses in the range of \$42 to \$44 million resulting primarily from the ESP Pharma and Retavase acquisitions. The revised R&D expenses do include an expenditure for our ularitide program for acute decompensated heart failure.

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In addition, we continue to expect interest income of approximately \$7 million and interest expense of approximately \$8 million.

Overall, for the full year 2005 we anticipate a GAAP net loss in the range of approximately \$1.30 to \$1.37 per basic and diluted share, and a non-GAAP net loss in the range of approximately 17 to 25 cents per basic and diluted share. We currently estimate the weighted average number of shares outstanding for the year at approximately 103.9 million.

As a result of the re-evaluation of our cash position, we now estimate that our year-end cash balances will exceed approximately \$180 million, a change from the prior estimate of \$200 million. This estimate takes into account anticipated capital expenditures of \$38 to \$42 million, approximately half of which represents final validation and completion of our new Brooklyn Park, Minnesota manufacturing facility; cash payments during 2005 of \$325 million and \$110 million for the acquisitions of ESP Pharma and Retavase, respectively; the receipt of approximately \$242 million from the February 2005 sale of convertible notes, net of fees and expenses; and the repayment of approximately \$14 million in ESP-related debt.

As PDL quickly evolves toward fully-integrated status with significantly higher operating revenues and expenses, consistent with our earlier guidance, we continue to expect to achieve positive cash flow from operations on a quarterly basis beginning in the second half of 2006. Consequently, you should join me in feeling very confident in the financial health of this rapidly growing enterprise.

At this time, I would like to turn the call over to Steve Benner, our Chief Medical Officer, for a discussion of recent clinical and regulatory developments, future milestones and upcoming data presentations.

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Dr. Steven Benner:

Thank you Glen.

Our team has never been more excited about the depth and progress of our clinical pipeline. Let's talk about why that's the case as we focus on the development of novel therapies that we expect will someday be aimed at hospital-based audiences in the US and elsewhere.

Beginning with Nuvion, our highest clinical priority, on March 22, PDL reported that it had discussed with the FDA, the future development pathway for Nuvion for the treatment of intravenous steroid-refractory ulcerative colitis. We had a productive and informative meeting from which we are developing a clear pathway for future development leading to what we hope will be the first ever BLA filing for PDL.

We now expect 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 and is expected to begin this year, along with the retreatment study. Assuming certain protocol-defined criteria are met at the time of the interim analysis, the second pivotal trial would be initiated. The proposed protocols are expected to be reviewed in detail by the FDA. We are currently planning to provide a further development update and set of timelines by the end of May 2005.

Dr. Stephan Targan of the Cedars-Sinai Division of Gastroenterology and Professor at the UCLA School of Medicine, will present additional data from an ongoing Phase I / II study of *Nuvion* in steroid-refractory ulcerative colitis in an oral presentation on May 17 beginning at 11:30 a.m. at the Digestive Disease Week meeting to be held in Chicago. Dr. Targan will discuss results from the four dose cohorts evaluated in the Phase I component of the study, which were 5, 7.5, 10 and 12.5 micrograms per

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kilogram, and will also plan on addressing available results from the retreatment of certain patients with Nuvion in accordance with the study protocol.

Moving on to daclizumab, last quarter as anticipated, we initiated a single-dose Phase I study of PDL-manufactured daclizumab administered subcutaneously in healthy volunteers. We expect to follow this trial with a multiple-dose study in healthy volunteers, which is currently slated to begin this summer. A Phase II dose range-finding study of subcutaneously administered, PDL-manufactured daclizumab in asthma patients remains on schedule to begin in the first quarter of 2006. In addition, we continue to evaluate the opportunity to develop daclizumab further in the setting of solid organ transplantation.

In MS, although we did not treat the first patient as hoped in the first quarter, our 270-patient, three-arm Phase II study is open and scheduled to enroll patients in this second quarter. In this study, patients with active relapsing forms of MS will receive subcutaneous daclizumab at 2 mg/kg every two

weeks or 1 mg/kg every four weeks, or placebo, for a total of six months in addition to their current beta-interferon treatment. We are simultaneously active in partnering discussions related to our stated corporate objective of establishing an MS collaboration by the end of this current quarter.

For ularitide, a compound developed by CardioPep Pharma GmbH to treat decompensated congestive heart failure, or DHF, we reported positive Phase II clinical results on April 18. The SIRIUS II trial was a randomized, double-blind, placebo-controlled clinical trial conducted by CardioPep at 19 centers in Europe. Primary endpoints in the study were change of pulmonary capillary wedge pressure, or PCWP, and change in dyspnea (shortness of breath) score, both at six hours. A total of 221 patients were randomized equally to receive ularitide 7.5, 15, or 30 ng/kg/min given intravenously as a 24-hour infusion, or placebo. In the assessment of the primary endpoints, ularitide significantly reduced PCWP ($p < 0.05$) and improved dyspnea score

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($p < 0.05$) in all three dose groups compared to placebo. The main adverse events through day three were dose-dependent decreases in blood pressure compared to placebo. Serum creatinine levels were unchanged during and after ularitide treatment when compared to placebo. The incidence of serious adverse events was similar for all three treatment groups and the placebo group.

DHF is a serious medical condition in which the heart is unable to maintain adequate circulation of blood in the tissues of the body or to pump out the venous blood returned to it by the venous circulation. In the United States alone, there are approximately one million hospitalizations per year for decompensated congestive heart failure.

Through the ESP Pharma acquisition, PDL acquired exclusive rights to conduct all subsequent development and exclusive marketing rights for ularitide for all indications in the United States, Canada, the European Union and Switzerland. To date, the clinical development of ularitide has taken place in Europe. We expect to file a U.S. Investigational New Drug, or IND, application this year, to allow clinical trials in both the United States and EU. We intend to give a further development update on ularitide at our R&D Update in the fall of this year, and we have submitted an abstract summarizing these data for possible presentation at the Scientific Meeting of the Heart Failure Society of America to be held September 18-21 at Boca Raton, Florida. We may additionally submit an abstract to the European Society of Cardiology Congress to be held in Stockholm, Sweden, September 3-7.

In cancer, we are conducting pilot Phase II clinical trials using M200 as an anti-angiogenic therapy for the treatment of solid tumors. Three trials are enrolling up to 40 patients per trial, and will further assess the tolerability of prolonged administration of M200 and look for evidence of clinical activity. An additional pilot Phase II study is

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expected to open in the second quarter of 2005. Data from at least two of the initial Phase II studies is expected to be available for presentation during the ASCO meeting in June 2006.

In addition, PDL plans to conduct a pilot Phase II trial of M200 administered intravenously in patients with age-related macular degeneration (AMD), which is expected to begin during the second half of 2005.

Finally, together with privately-held Orphan Therapeutics, we recently reported that the FDA had granted Fast Track status to the development of terlipressin for the treatment of patients with type 1 hepatorenal syndrome (HRS). HRS is the development of a functional renal failure in patients with end-stage liver disease in the absence of any other cause of renal pathology. Type 1 HRS is characterized by rapid deterioration of renal function, with a median survival time of less than two weeks, unless liver transplantation is performed. The current treatment of choice in the US is liver transplantation, if the patient is suitable for transplantation and survives until a transplant is available.

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 the product nor does it increase the likelihood of approval of the product.

Through the acquisition of ESP Pharma, we acquired exclusive marketing, sales and distribution rights for terlipressin in the United States and Canada. Orphan Therapeutics holds the U.S. IND for terlipressin and is conducting a Phase III clinical trial in the United States and Europe for type 1 HRS. Orphan Therapeutics has obtained Orphan Drug Status for this program.

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As you can see, it's been a very busy but exciting quarter on all fronts for PDL.

At this time, I'd like to turn the call back over to Jim Goff.

Jim Goff:

Thank you, Steve. That concludes our prepared presentations. Operator, please begin the Q and A.

Before we close I will note our schedule of upcoming presentations. Glen Sato will be presenting tomorrow, May 3 at the Deutsche Bank Conference in Baltimore; Dr. Targan will be presenting data at DDW in Chicago on May 17 at 11:30 a.m.; Glen Sato will present at the Needham & Company conference on May 25 in New York and at the Pacific Growth Equities Life Sciences Growth Conference in San Francisco on June 6. Mark McDade will present at the Goldman Sachs conference in Laguna Niguel on June 14. In closing, a reminder that our annual shareholder meeting will be held June 8 in New York. We look forward to seeing many of you at these important events.

Thank you, and good afternoon.

