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):
November 1, 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 2.02. Results of Operations and Financial Condition

On November 1, 2004, the Company issued a press release (the "Press Release") announcing the Company's financial results for the fiscal quarter ended September 30, 2004 (the "Results"). The Press Release is attached as Exhibit 99.1 to this Current report on Form 8-K and is incorporated herein by reference.

Use of Non-GAAP Financial Information

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

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 1, 2004, regarding the third quarter 2004 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.

PROTEIN DESIGN LABS, INC.

Date: November 1, 2004

By: /s/ Sergio Garcia-Rodriguez

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

www.pdl.com

For Immediate Release

Contact:

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PROTEIN DESIGN LABS ANNOUNCES THIRD QUARTER 2004 FINANCIAL RESULTS

Raises full-year 2004 revenue guidance to $93-$95 million from $88-$91 million

Fremont, Calif., November 1, 2004 - Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported a net loss of $13.6 million, or $0.14 per basic and diluted share, for the three months ended September 30, 2004, compared with a net loss of $18.9 million, or $0.20 per basic and diluted share, for the three months ended September 30, 2003. Excluding certain non-cash charges, the non-GAAP net loss in the third quarter of 2004 would have been $12.6 million, or $0.13 per basic and diluted share, compared with a non-GAAP net loss of $18.6 million, or $0.20 per basic and diluted share in the 2003 third quarter.

As of September 30, 2004, PDL had cash, cash equivalents, marketable securities and restricted investments totaling approximately $425.8 million, compared with $505.0 million at December 31, 2003. The September 30, 2004 balances reflected approximately $80.7 million in capital expenditures made during the first nine months of 2004, primarily related to budgeted, ongoing construction of PDL's manufacturing plant at Brooklyn Park, Minnesota.

Total revenues in the 2004 third quarter were $19.8 million, an increase of 112% over total revenues of $9.3 million in the same three months of 2003. The increase included a 96% increase in royalties, which totaled $17.1 million in the 2004 third quarter, compared with $8.8 million in the same three months of 2003. License and other revenues of $2.7 million increased from $0.6 million in the prior-year period as a result of entering into additional collaboration agreements in the third quarter of 2004, including approximately $1.2 million related to one month of revenue under the September 2004 agreement with Roche for the further development and commercialization of Zenapax® (daclizumab) in asthma and related respiratory diseases, and $1.0 million in revenue related to a patent rights agreement with Morphotek, Inc.

Royalty revenues in the 2004 third quarter were based on sales of seven marketed antibody products licensed under PDL's antibody humanization patents. The licensed products are Synagis® from MedImmune, Inc.; Herceptin®, Xolair®, RAPTIVA™ and Avastin™ from Genentech, Inc.; Mylotarg® from Wyeth; and Zenapax from Roche. Higher royalty revenues in the third quarter of 2004 compared to the same period in 2003 primarily were due to significant sales of Avastin and continued sales growth of Herceptin. Royalty revenues in the 2003 third quarter did not include royalties on Avastin, Xolair and RAPTIVA.

Total costs and expenses were $35.0 million in the 2004 third quarter, compared with $28.8 million in the comparable three months of 2003. Excluding certain non-cash charges, which consist of the amortization of intangible assets associated with the Eos acquisition and the re-acquisition of rights to manufacture and market Zenapax in the fourth quarter of 2003, restructuring charges related to the closure of PDL's New Jersey facility in the second quarter of 2004, as well as stock-based compensation charges, non-GAAP total costs and expenses in the 2004 third quarter would have been $34.0 million compared to $28.5 million for the comparable period in 2003.

Research and development expenses increased 25% to $27.3 million in the 2004 third quarter, compared with $21.8 million in the 2003 third quarter. 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; increased research activities; and facility and equipment-related costs. General and administrative expenses increased to $7.7 million in the 2004 third quarter from $7.0 million in the 2003 third quarter.

Total revenues during the first nine months of 2004 were $73.2 million, compared with $53.1 million in the first nine months of 2003. Royalties in the first nine months this year were $63.9 million, or 46% higher than the $43.8 million of royalties reported in the first nine months of 2003. Research and development expenses were $92.4 million in the first nine months of 2004, compared with $58.3 million in the comparable nine months of 2003. General and administrative expenses were $23.2 million and $19.5 million in the first nine months of 2004 and 2003, respectively. PDL reported a net loss of $38.7 million, or $0.41 per basic and diluted share, for the first nine months of 2004, compared with a net loss of $57.0 million, or $0.62 per basic and diluted share, in the first nine months of 2003, which included an acquired in-process research and development charge of $37.8 million. Excluding certain non-cash charges, the non-GAAP net loss in the first nine months of 2004 would have been $35.7 million, or $0.38 per basic and diluted share, compared with a non-GAAP net loss of $18.5 million, or $0.20 per basic and diluted share in the comparable period of 2003.

Third Quarter 2004 Clinical Development Highlights

Nuvion® Antibody Product (visilizumab, humanized anti-CD3). Interim results from the Phase I dose-ranging portion of a Phase I / II clinical trial of visilizumab in patients with severe ulcerative colitis who have not responded to treatment with intravenous (I.V.) steroids were reported in late September 2004. The ongoing trial is designed to explore four dose levels from 5 µg/kg to 12.5 µg/kg given I.V. on days 1 and 2 as a bolus injection. Following the Phase I portion of the study, PDL plans to treat up to an additional 20 patients in the Phase II portion.

The interim Phase I data assessed a total of 50 patients for safety across the 5, 7.5, 10 and 12.5 µg/kg doses. In the 5, 7.5 and 10 µg/kg doses, 30 patients were also evaluable for efficacy at study day 30.

PDL reported that visilizumab was generally well tolerated and that at the 5, 7.5 and 10 µg/kg doses, 63% of the patients evaluated at day 30 had improved mucosal scores to normal, or only mildly abnormal, findings.

In a completed, 32-patient Phase I study of two dose cohorts that was reported in May 2004, a strong signal of activity was observed in the first dose cohort given at 15 µg/kg on days 1 and 2, in which all eight patients achieved remission. A continued strong signal of activity subsequently was observed in the second dose cohort given at 10 µg/kg administered I.V. on days 1 and 2. At the 10 µg/kg dose level, 19 of 24 patients responded to treatment and of these, 13 achieved remission.

PDL additionally announced in late September that the FDA had granted Fast Track status to the investigation of visilizumab in patients with intravenous steroid-refractory ulcerative colitis. 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.

PDL currently plans to conduct an end-of-Phase I meeting with the FDA in the first quarter of 2005.

Daclizumab (Zenapax®, anti-CD25). PDL and Roche in September announced a worldwide agreement to co-develop and commercialize Zenapax® (daclizumab) for asthma and related respiratory diseases, based on recent positive Phase II data in patients with moderate to severe asthma. Under terms of the agreement, PDL has received a $17.5 million upfront payment and may receive up to $187.5 million in 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 United States. Outside the United States, PDL will receive royalties on net sales of the product in asthma and related respiratory diseases.

In March 2004, PDL reported positive results from the initial clinical study of daclizumab in patients with chronic, persistent asthma whose disease is not well controlled with high doses of inhaled corticosteroids. There were statistically significant treatment differences (p=0.05) observed for the primary endpoint, percent change in FEV_1 from baseline to 12 weeks (day 84). Secondary clinical endpoints also supported these findings. Treatment with daclizumab was generally well tolerated. PDL currently expects that the next trial of daclizumab in asthma will be a small Phase I clinical trial intended to gather additional experience with the PDL-manufactured subcutaneous formulation of daclizumab in healthy volunteers, and should begin in the fourth quarter of this year. The company expects that a subsequent Phase IIb clinical trial in moderate-to-severe persistent asthma should begin by the third quarter of 2005.

Preparatory work for a PDL study of daclizumab in multiple sclerosis (MS) continues, and the company currently plans to initiate a Phase II study in MS in the first quarter of 2005.

M200 (anti-alpha5beta1 integrin antibody). PDL in September presented interim clinical data from a Phase I dose-escalation study of M200 for the treatment of refractory solid tumors. M200 is an anti-angiogenic antibody that targets the endothelium of tumor neovasculature.

Sixteen men and women between the ages of 29 and 81 (mean 58 years) with various solid tumor types refractory to standard therapy have been enrolled in this study. Tumor types included colorectal, melanoma, hepatic, pancreatic and non-small cell lung cancers. Patients were enrolled into dose cohorts as follows: one patient at 0.5 mg/kg, 2 patients at 1 mg/kg, 3 patients at 2.5 mg/kg, 3 patients at 5.0 mg/kg and 6 patients at 10 mg/kg. Each patient received 5 doses of M200 on study days 1, 15, 22, 29, and 36. The study data showed that adverse events were generally mild to moderate in intensity and included fatigue, nausea, constipation, headache, and anorexia. There were no severe or serious adverse events that were dose limiting or considered by investigators to be related to M200.

In addition, 10 of 15 evaluable patients had stable disease as their best response, and five of six patients treated at the highest dose level, 10 mg/kg, achieved stable disease. Four patients with stable disease after 5 doses of M200 in the Phase I study continued treatment with M200 in a Phase I extension study. Three of these patients maintained stable disease for greater than 16 weeks over the two studies.

PDL plans to initiate over the next few quarters a series of open-label, Phase II trials in renal, melanoma, pancreatic, and non-small cell lung cancers in both combination studies with chemotherapy as well as single-agent use.

F200 (anti-alpha5beta1 integrin antibody fragment). PDL in early October reported preclinical data which demonstrated that F200 can inhibit retinal neovascularization induced by multiple growth factors, such as VEGF and bFGF, and supports previous data which demonstrated that F200 can block neovascularization in an experimental CNV animal model. PDL currently expects to enter F200 into clinical trials by year-end 2005 for the potential treatment of age-related macular degeneration (AMD).

Outlook

The following statements are based on expectations as of November 1, 2004. These statements are forward-looking, and actual results may differ materially. Except as expressly set forth below, these statements do not include the potential impact of new collaborations, material licensing arrangements or other strategic transactions.

As we previously indicated, the signing of our corporate collaboration involving Zenapax in asthma with Hoffmann-La Roche (Roche) in the quarter as well as the continued strong initial sales of Genentech's Avastin antibody product will result in a significant favorable increase in financial guidance for the year. As we noted on our September 16, 2004 conference call describing in more detail the Roche collaboration, the upfront $17.5 million payment received from Roche in September will be amortized over a period of six years, and reimbursement of half of the research expenses related to the U.S. asthma development program

and manufacturing is being recognized as revenue in the License and Other Income line of our Consolidated Statements of Operations, effective September 1, 2004.

We are updating our financial guidance for 2004 compared to 2003 with expectations compared to December 31, 2003 non-GAAP performance as follows: (a) total revenues are expected to be in the range of $93 to $95 million, an increase of approximately 39-42% compared to total revenues in 2003; (b) interest income for the year to total approximately $10 million and interest expense of approximately $5 million; (c) total costs and expenses of approximately $149 to $154 million, an increase of approximately 35-40% in 2004 compared with total costs and expenses in 2003; and (d) capital expenditures in the range of approximately $88 million to $93 million in 2004. Approximately $20 million of capital expenditures related to completion and validation of our Brooklyn Park facility are now anticipated to be delayed in 2004 and are therefore expected to be incurred in 2005. As a result, we expect a net loss in 2004 in the range of approximately $52.0 million to $57.0 million, or approximately $0.55 to $0.60 per basic and diluted share. We continue to expect total full-time employee headcount to be in the range of 650-675 at year-end 2004.

Finally, we anticipate having available cash, cash equivalents, marketable securities and restricted investments of approximately $400 million at the end of 2004. The change from previous end-of-year cash guidance is attributable to the Roche transaction, to improved overall royalty revenues and to significant cash arising from the Employee Stock Purchase Plan and stock option exercises.

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its third quarter 2004 financial results. 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 at approximately 6:30 p.m. Eastern time on November 1. A replay of the conference call will also be available by telephone from approximately 6:30 p.m. Eastern time on November 1 through 6:30 p.m. Eastern time on November 4, 2004. 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 21212418.

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. Factors that may cause differences between current expectations and actual results include, but are not limited to, the following: Financial results for 2004 are unpredictable and may fluctuate from quarter to quarter. PDL expenses, in principal part, depend on the total headcount of the organization and the timing of expenses. PDL revenues depend on the success and timing of sales of our licensees and partners, including in particular the continued successful launch of Avastin antibody product by Genentech, as well as the seasonality of sales of Synagis from MedImmune, Inc. In addition, quarterly revenues may be impacted by our ability to maintain and increase our revenues from licensing, which revenues depend on third parties entering into new patent licensing arrangements, exercising rights under existing patent rights agreements, paying royalties under existing patent licenses and the timing of the recognition of revenues under any new and existing agreements. Our revenues and expenses would also be affected by the continuation of our asthma collaboration with Roche, new collaborations, material patent licensing arrangements or other strategic transactions.

Further, there can be no assurance that results from completed and ongoing clinical studies, described above, will be successful or completed or initiated on the anticipated schedules. Other factors that may cause our actual results to differ materially from those, express or implied, in the forward-looking statements in this press release are discussed in our Annual Report on Form 10-K for the year ended December 31, 2003, in our quarterly report on Form 10-Q for the period ended June 30, 2004, and in other 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.

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.

Financial tables attached.

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

(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Revenues:				
Royalties	$ 17,131	$ 8,758	$ 63,872	$ 43,808

License and other	2,653	567	9,323	9,265
Total revenues	19,784	9,325	73,195	53,073
Costs and expenses:				
Research and development	27,326	21,812	92,364	58,323
General and administrative	7,664	6,963	23,182	19,465
Acquired in-process research and development	—	—	—	37,834
Total costs and expenses	34,990	28,775	115,546	115,622
Operating loss	(15,206)	(19,450)	(42,351)	(62,549)
Interest and other income, net	2,822	4,291	7,689	13,151
Interest expense	(1,193)	(3,705)	(3,929)	(7,346)
Impairment loss on investment	—	—	—	(150)
Loss before income taxes	(13,577)	(18,864)	(38,591)	(56,894)
Provision for income taxes	12	11	68	60
Net loss	$(13,589)	$(18,875)	$(38,659)	$(56,954)
Net loss per basic and diluted share:	$ (0.14)	$ (0.20)	$ (0.41)	$ (0.62)
Shares used in computation of net loss per basic and diluted share:	95,196	93,665	94,771	92,049

CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

(In thousands)	September 30, 2004	December 31, 2003*
	(unaudited)	
Cash, cash equivalents, marketable securities and restricted investments	$425,797	$504,993
Total assets	727,780	742,030
Total stockholders' equity	423,717	448,331

* Derived from the December, 2003 audited consolidated financial statements.

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

We use non-GAAP amounts that exclude certain non-cash charges, including amounts related to the amortization of intangible assets and stock-based compensation. 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. Our management uses these non-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 September 30,					
	2004			2003		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Royalties	$ 17,131		$ 17,131	$ 8,758		$ 8,758
License and other	2,653		2,653	567		567
Total revenues	19,784		19,784	9,325		9,325
Costs and expenses:						
Research and development	27,326	(958) (1)	26,368	21,812	(217) (2)	21,595

General and administrative	7,664	(14) (1)	7,650	6,963	(14) (2)	6,949
Acquired in-process research and development	-		-	-		-
Total costs and expenses	34,990	(972)	34,018	28,775	(231)	28,544
Operating loss	(15,206)	972	(14,234)	(19,450)	231	(19,219)
Interest and other income, net	2,822		2,822	4,291		4,291
Interest expense	(1,193)		(1,193)	(3,705)		(3,705)
Impairment loss on investment	-		-	-		-
Loss before income taxes	(13,577)	972	(12,605)	(18,864)	231	(18,633)
Provision for income taxes	12		12	11		11
Net loss	$ (13,589)	$ 972	$ (12,617)	$ (18,875)	$ 231	$ (18,644)
Net loss per basic and diluted share:	$ (0.14)		$ (0.13)	$ (0.20)		$ (0.20)
Shares used in computation of net loss per basic and diluted share:	95,196		95,196	93,665		93,665

(1) To exclude (i) the ongoing, non-cash amortization of acquired net intangible assets, including workforce, related to the Eos acquisition, and core technology, related to the purchase of certain patent rights from Roche, (ii) the restructuring charges related to the closure of our New Jersey facility and (iii) stock-based compensation charges related to stock options issued to non-employees and modifications to certain employee stock options.

(2) To exclude (i) the ongoing, non-cash amortization of acquired net intangible assets, including workforce, related to the Eos acquisition, and (ii) stock-based compensation charges related to stock options issued to non-employees.

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

We use non-GAAP amounts that exclude certain non-cash charges, including amounts related to the amortization of intangible assets and stock-based compensation. 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. Our management uses these non-GAAP financial measures in evaluating the Company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)

	Nine months ended September 30,					
	2004			2003		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Royalties	$ 63,872		$ 63,872	$ 43,808		$ 43,808
License and other	9,323		9,323	9,265		9,265
Total revenues	73,195		73,195	53,073		53,073
Costs and expenses:						
Research and development	92,364	(2,954) (1)	89,410	58,323	(579) (2)	57,744
General and administrative	23,182	(42) (1)	23,140	19,465	(28) (2)	19,437
Acquired in-process research and development	-		-	37,834	(37,834) (3)	-
Total costs and expenses	115,546	(2,996)	112,550	115,622	(38,441)	77,181
Operating loss	(42,351)	2,996	(39,355)	(62,549)	38,441	(24,108)
Interest and other income, net	7,689		7,689	13,151		8,861
Interest expense	(3,929)		(3,929)	(7,346)		(7,346)
Impairment loss on investment	-		-	(150)		(150)
Income (loss) before income taxes	(38,591)	2,996	(35,595)	(56,894)	38,441	(18,453)

Provision for income taxes	68		68	60		60
Net loss	$ (38,659)	$ 2,996	$ (35,663)	$ (56,954)	$ 38,441	$ (18,513)
Net loss per basic and diluted share:	$ (0.41)		$ (0.38)	$ (0.62)		$ (0.20)
Shares used in computation of net loss per basic and diluted share:	94,771		94,771	92,049		92,049

(1) To exclude (i) the ongoing, non-cash amortization of acquired net intangible assets, including workforce, related to the Eos acquisition, and core technology, related to the purchase of certain patent rights from Roche, (ii) the restructuring charges related to the closure of our New Jersey facility and (iii) stock-based compensation charges related to stock options issued to non-employees and modifications to certain employee stock options.

(2) To exclude (i) the ongoing, non-cash amortization of acquired net intangible assets, including workforce, related to the Eos acquisition, and (ii) stock-based compensation charges related to stock options issued to non-employees.

(3) To exclude the non-cash charge of acquired in-process research and development, related to the Eos acquisition.