
**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 4, 2004**

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

000-19756
(Commission File Number)

94-3023969
(IRS Employer Identification No.)

34801 Campus Drive
Fremont, California 94555
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(510) 574-1400**

Not Applicable
(Former name or former address, if changed since last report)

Item 7. Financial Statements and Exhibits

(c) Exhibits

99.1 Press Release, dated May 4, 2004, regarding the first quarter 2004 financial results of Protein Design Labs, Inc.

Exhibit 99.1 attached hereto (i) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (ii) shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language contained in such filing, except as shall be expressly set forth by specific reference in such filing, and (iii) shall not be deemed to be subject to the liabilities of Sections 11, 12(a)(2) or 18 of the Securities Act of 1933, as amended.

Item 12. Results of Operations and Financial Condition.

On May 4, 2004, Protein Design Labs, Inc. (the "Company") announced its financial results for the fiscal quarter ended March 31, 2004. A copy of the Company's press release relating to the financial results for the fiscal quarter ended March 31, 2004 is attached hereto as Exhibit 99.1.

The information furnished in this Item 12 and Exhibit 99.1 attached hereto (i) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (ii) shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language contained in such filing, except as shall be expressly set forth by specific reference in such filing, and (iii) shall not be deemed to be subject to the liabilities of Sections 11, 12(a)(2) or 18 of the Securities Act of 1933, as amended.

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.

SIGNATURES

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

PROTEIN DESIGN LABS, INC.

Date: May 6, 2004

By: /s/ Sergio Garcia-Rodriguez
Sergio Garcia-Rodriguez
Vice President, Legal, General Counsel and
Assistant Secretary

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 4, 2004, regarding the first quarter 2004 financial results of Protein Design Labs, Inc.

Contact:

James R. Goff
Senior Director,
Corporate Communications
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**PROTEIN DESIGN LABS ANNOUNCES FIRST QUARTER 2004
FINANCIAL RESULTS**

Fremont, Calif., May 4, 2004 — Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported a net loss of \$12.6 million, or \$0.13 per basic and diluted share, for the three months ended March 31, 2004, compared with net income of \$4.1 million, or \$0.05 per basic and diluted share, for the three months ended March 31, 2003. Excluding certain non-cash charges, the non-GAAP net loss in the first quarter of 2004 would have been \$12.0 million, or \$0.13 per basic and diluted share.

On March 31, 2004, PDL had cash, cash equivalents, marketable securities and restricted investments totaling approximately \$466.9 million, compared with \$505.0 million at December 31, 2003. The March 31, 2004 balances reflected approximately \$33.2 million in capital expenditures in the 2004 first quarter primarily related to purchases of property, plant and equipment for the ongoing construction of PDL's manufacturing plant at Brooklyn Park, Minnesota.

PDL reported total revenues of \$27.6 million in the first quarter of 2004, an increase of 21% over total revenues of \$22.7 million in the first three months of 2003. The increase primarily reflected a 28% increase in royalties, which totaled \$22.0 million in the 2004 first quarter, compared with \$17.1 million in the same three months of 2003. Royalty revenues in the 2004 first quarter were based on sales of six marketed antibody products licensed under PDL's antibody humanization patents: Synagis® from MedImmune, Inc.; Herceptin®, Xolair® and RAPTIVA™ from Genentech, Inc.; Mylotarg® from Wyeth; and Zenapax® from Roche. Higher royalty revenues in the first quarter of 2004 primarily were due to significant sales growth of both Herceptin and Synagis. Royalty revenues in the 2003 first quarter did not include royalties on Xolair and RAPTIVA, antibody products which Genentech licensed under PDL's humanization patents in the fourth quarter of 2003. Genentech also exercised a license for its Avastin™ antibody product in the first quarter of 2004, for which PDL received and recognized a license exercise fee in excess of \$1.0 million. PDL expects to recognize royalties under that license commencing in the second quarter of this year. License and other revenue in the first quarter of 2004 remained essentially unchanged from the comparable quarter in 2003, and included \$3.0 million in revenue from a collaboration with Seattle Genetics, Inc. (SGI) described below.

Protein Design Labs, Inc.

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Total costs and expenses were \$41.1 million in the 2004 first quarter, compared with \$21.3 million in the first three months of 2003. Excluding certain non-cash charges, which consisted primarily of the amortization of intangible assets associated with the acquisition of Eos Biotechnology, Inc. during the second quarter of 2003 and the re-acquisition of rights to manufacture and market Zenapax in the fourth quarter of 2003, non-GAAP total costs and expenses in the 2004 first quarter would have been \$40.5 million. Research and development expenses increased 107% to \$33.0 million in the 2004 first quarter, compared with \$16.0 million in the 2003 first quarter. General and administrative expenses increased to \$8.1 million in the 2004 first quarter from \$5.3 million in the 2003 first quarter.

The increases in total costs and expenses reflected the growth in the company's clinical development pipeline and investment in commercial manufacturing capacity. More specifically, costs and expenses in the 2004 first quarter reflected additional headcount required to pursue research and clinical development programs; expanded and larger-scale clinical trial activity; increased research activities, including \$3.5 million of expenses from a collaboration with SGI; direct scale-up and manufacturing expenses; facility and equipment-related costs and contract manufacturing expense.

During the first quarter of 2004, PDL entered into a transaction with SGI in which PDL granted patent rights and a patent license to SGI under PDL's humanization patents, in addition to making a \$0.5 million cash payment, in exchange for expanded access to SGI's drug conjugate and linker technology. The transaction was an expansion of a previously existing arrangement with SGI. In connection with the agreements, PDL recognized research and development expense of \$3.5 million, and recognized license revenue of \$3.0 million.

First Quarter 2004 Clinical Development Highlights

Nuvion® Antibody Product (visilizumab, humanized anti-CD3). Preliminary findings from a Phase I clinical trial of visilizumab in patients with severe ulcerative colitis who have not responded to treatment with intravenous (I.V.) steroids were reported in March 2004. A strong signal of activity in the Phase I trial was observed in the first dose cohort, given at 15 mg/kg on days 1 and 2, in which all eight patients responded and seven of eight achieved remission. A continued strong signal of activity subsequently has been observed in the second dose cohort given at 10 mg/kg given I.V. on days 1 and 2. To date, a total 17 of the 20 evaluable patients in the second dose cohort have responded to treatment, and of these, 11 achieved remission. The visilizumab Phase I study is now closed to further enrollment with 32 patients enrolled. Scott Plevy, M.D., Associate Professor of Medicine, University of Pittsburgh, will present results of the Phase I study in an oral presentation at 2:15 p.m. Central time on May 18 at the 2004 Digestive Disease Week (DDW) meeting in New Orleans.

PDL is actively accruing patients into an ongoing Phase I/II trial of visilizumab in the severe ulcerative colitis setting. This trial, initiated in the fourth quarter of 2003, is designed to explore four dose levels of Nuvion from 5 mg/kg to 12.5 mg/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.

Currently, we anticipate that the Phase I trial and Phase I portion of the Phase I/II trial may serve as the basis for discussions with regulatory agencies in the second half of 2004 regarding the design of possible registrational trials.

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Daclizumab (Zenapax[®], anti-CD25). 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. The primary endpoint, percent change in FEV₁ from baseline to 12 weeks (day 84), met statistical significance (p=0.05). Secondary clinical endpoints also supported these findings. The Phase II randomized, double-blind, placebo-controlled clinical trial was conducted at 24 centers in the United States and treated a total of 114 patients. In the assessment of the primary endpoint, patients receiving daclizumab experienced a mean increase in FEV₁, of 4.4% of baseline, compared to placebo patients who experienced a mean decrease of 1.5% (p=0.05). FEV₁ or forced expiratory volume of air in one second, is a measure of pulmonary function. Treatment with daclizumab was generally well tolerated. The overall frequency and severity of adverse events did not differ between daclizumab and placebo groups. PDL currently expects that the next trial of daclizumab in asthma will be a Phase II trial in which daclizumab is administered subcutaneously.

Patient enrollment into a Phase II clinical trial of daclizumab in the setting of moderate-to-severe ulcerative colitis was completed in the fourth quarter of 2003. PDL anticipates that results from this trial will be available by the time of the 2004 DDW meeting in mid-May. Preparatory work for a PDL study of daclizumab in multiple sclerosis continues.

HuZAF[™] Antibody Product (fontolizumab, anti-gamma interferon). In March 2004, PDL reported results of two randomized, placebo-controlled, double-blind trials of fontolizumab (HuZAF[™]) in Crohn's disease. The first study (HARMONY[™] I) explored an initial I.V. dose of HuZAF given as 1 mg/kg or 4 mg/kg. In the second trial (HARMONY[™] II), patients received up to two I.V. doses of HuZAF given at 4 mg/kg or 10 mg/kg. The primary endpoint for both trials was the response to the initial I.V. dose. PDL reported that HuZAF did not meet the primary endpoint at study day 28 in either trial following administration of a single intravenous dose. HuZAF, however, demonstrated statistically greater activity compared to placebo at several subsequent time points following administration of a second intravenous dose in the HARMONY II clinical trial. Results from the HARMONY II clinical trial have been accepted for presentation as a late-breaking abstract at the 2004 DDW Meeting. D. W. Hommes, M.D., Ph.D., affiliated with the Research Center for Inflammatory Bowel Diseases at the Academic Medical Center in Amsterdam, The Netherlands, will present the HARMONY II study in an oral presentation at 9:30 a.m. Central time on May 19 at the DDW meeting.

M200 (anti-alpha5beta1 integrin antibody). PDL continues to enroll patients in a Phase I, dose-escalation study of M200, its anti-alpha5beta1 integrin antibody. This anti-angiogenic antibody targets the endothelium of tumor neovasculature and is being developed as a treatment for solid tumors. Phase II trials are expected to begin late in 2004.

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Outlook

The following statements are based on expectations as of May 4, 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.

Since our results are substantially dependent on royalty revenues from our licensees and the timing of entry into new collaborative arrangements, for 2004 we expect to provide guidance only for the year and not on a quarterly basis as increases in our revenues will be dependent on the continued success of licensed antibody products, including three recently licensed Genentech antibody products, Xolair, RAPTIVA and Avastin.

We want to emphasize that we have not changed our financial guidance for 2004 compared to 2003, originally provided in February 2004, with expectations compared to December 31, 2003 non-GAAP performance. We reiterate our guidance as follows: (a) total revenues will increase by approximately 17-22% compared to total revenues in 2003, inclusive of an approximate 30% annual increase in royalty revenues from 2003 levels; (b) interest income for the year to total approximately \$11 million to \$13 million; (c) total costs and expenses increasing by approximately 39-44% in 2004 compared with total costs and expenses in 2003; and capital expenditures in the range of approximately \$100 million to \$110 million in 2004 (of which approximately \$85 million to \$90 million are expected to be related to construction of our new manufacturing center at Brooklyn Park, Minn, which will represent substantially all of the initially contemplated capital investment in our new manufacturing center). As a result, we continue to expect a net loss in 2004 in the range of approximately \$70 million to \$75 million, or approximately \$0.74 to \$0.79 per basic and diluted share.

Finally, we anticipate having available cash, restricted cash and investments, cash equivalents and marketable securities of approximately \$345 million at the end of 2004.

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its first 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 May 4. A replay of the conference call will also be available by telephone from approximately 6:30 p.m. Eastern time on May 4 through 6:30 p.m. Eastern time on May 7, 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 21193927.

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

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licensees and partners, including in particular the 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 new collaborations, material patent licensing arrangements or other strategic transactions.

Further, there can be no assurance that results from ongoing Phase I and Phase I/II studies of visilizumab, further Phase II clinical studies of daclizumab and fontolizumab, and the Phase I study of M200 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, 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.

Protein Design Labs, Humanizing Science and Nuvion are registered U.S. trademarks and the PDL logo and HuZAF are trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche. Synagis is a registered U.S. trademark of MedImmune, Inc. Herceptin and Xolair are registered U.S. trademarks and RAPTIVA and Avastin are trademarks of Genentech, Inc. Mylotarg is a registered U.S. trademark of Wyeth.

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,	
	2004	2003
Revenues:		
Royalties	\$ 22,010	\$ 17,145
License and other	5,618	5,602
Total revenues	27,628	22,747
Costs and expenses:		
Research and development	33,029	15,973
General and administrative	8,068	5,309
Total costs and expenses	41,097	21,282
Operating income (loss)	(13,469)	1,465
Interest and other income, net	2,284	4,672
Interest expense	(1,385)	(1,886)
Impairment loss on investment	—	(150)
Income (loss) before income taxes	(12,570)	4,101
Provision for income taxes	48	32
Net income (loss)	\$ (12,618)	\$ 4,069
Basic and diluted net income (loss) per share	\$ (0.13)	\$ 0.05
Shares used in computation of basic net income (loss) per share	94,000	89,182
Shares used in computation of diluted net income (loss) per share	94,000	90,150

CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

(In thousands)	March 31, 2004	December 31, 2003*
Cash, cash equivalents, marketable securities and restricted investments	\$ 466,857	\$ 504,993
Total assets	730,052	742,030
Total stockholders' equity	438,105	448,331

*Derived from the December 31, 2003 audited consolidated financial statements.

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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 March 31,			2003 GAAP
	2004 GAAP	Adjustments	Non-GAAP	
Revenues:				
Royalties	\$ 22,010		\$ 22,010	\$ 17,145
License and other	5,618		5,618	5,602
Total revenues	27,628		27,628	22,747
Costs and expenses:				
Research and development	33,029	\$ (619)(1)	32,410	15,973
General and administrative	8,068	(14)(1)	8,054	5,309
Total costs and expenses	41,097	(633)	40,464	21,282
Operating income (loss)	(13,469)	633	(12,836)	1,465
Interest income and other income, net	2,284	—	2,284	4,672
Interest expense	(1,385)	—	(1,385)	(1,886)
Impairment loss on investment	—	—	—	(150)
Income (loss) before income taxes	(12,570)	633	(11,937)	4,101
Provision for income taxes	48	—	48	32
Net income (loss)	\$ (12,618)	\$ 633	\$ (11,985)	\$ 4,069
Basic and diluted net income (loss) per share	\$ (0.13)		\$ (0.13)	\$ 0.05
Shares used in computation of basic net income (loss) per share	94,000		94,000	89,182
Shares used in computation of diluted net income (loss) per share	94,000		94,000	90,150

(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 and (ii) stock-based compensation charges related to stock options issued to non-employees.