
**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): **February 26, 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 12. Results of Operations and Financial Condition

On February 26, 2004, Protein Design Labs, Inc. ("PDL" or the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2003 and for the fourth quarter ended December 31, 2003. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein. The information furnished in this Item 12 and Exhibit 99.1 attached hereto shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 or 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be deemed to be incorporated by reference into any filing with the SEC made by PDL whether before or after the date hereof, regardless of any general incorporation language contained in such filing.

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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: March 17, 2004

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

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EXHIBIT INDEX

Exhibit No.

Description

Protein Design Labs Announces Full-Year and Fourth Quarter 2003 Financial Results

Fremont, CA

February 26, 2004

Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported a net loss of \$129.8 million, or \$1.40 per basic and diluted share, for the year ended December 31, 2003, compared with a net loss of \$14.6 million, or \$0.16 per basic and diluted share, for the year ended December 31, 2002. Excluding certain non-cash and acquisition and in-licensing charges (non-GAAP adjustments), the non-GAAP net loss in 2003 would have been \$35.9 million, or \$0.39 per basic and diluted share.

At December 31, 2003, PDL had cash, restricted cash and investments, cash equivalents and marketable securities totaling approximately \$505.0 million, compared with \$606.4 million at December 31, 2002. The December 31, 2003 balances reflect cash outlays within budget for capital expenditures in 2003 of approximately \$91 million principally related to construction of PDL's manufacturing plant at Brooklyn Park, Minn., \$80 million used to repurchase rights to market and manufacture Zenapax® (daclizumab), and approximately \$154 million used to redeem all of PDL's outstanding 5.50% Convertible Subordinated Notes with a principal amount of \$150 million. In July 2003, PDL raised approximately \$250 million through the issuance of Convertible Subordinated Notes due in 2023 with an initial redemption date in 2010 that bear interest at a rate of 2.75% per year.

The non-GAAP adjustments totaled \$93.9 million in 2003, consisting primarily of acquired in-process research and development of \$37.8 million associated with the acquisition of Eos Biotechnology, Inc. (Eos), \$48.2 million associated with the repurchase from Hoffmann-La Roche (Roche) of rights to market and manufacture Zenapax in indications other than transplantation and \$6.5 million related to the fourth-quarter redemption of its 5.50% Convertible Subordinated Notes with a principal amount of \$150 million.

In 2003, PDL reported total revenues of \$66.7 million, an increase of 44% over total revenues of \$46.4 million in 2002. The increase primarily reflected a 30% increase in royalties, which totaled \$52.7 million in 2003, compared with \$40.4 million in 2002. Royalty revenues in 2003 were based on sales of five marketed antibody products licensed under PDL's antibody humanization patents: Synagis® from MedImmune, Inc., Herceptin® and Xolair® from Genentech, Inc., Mylotarg® from Wyeth, and Zenapax. Higher royalty revenues in 2003 were due primarily to significant sales growth of both Herceptin and Synagis. Revenues in 2002 did not include royalties on Xolair, which antibody product Genentech launched in the third quarter 2003, and licensed under PDL's humanization patents in the fourth quarter 2003. Additionally, Genentech in the fourth quarter 2003 exercised a license for its Raptiva™ antibody product and PDL expects to receive royalties on sales of Raptiva beginning in the first quarter of 2004. Genentech also has agreed to exercise a license for its Avastin™ antibody product, contingent upon approval of that product by the U.S. Food and Drug Administration (FDA), which agency currently is conducting a priority review with an end of the first quarter 2004 action date.

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Research and development expenses increased 43% to \$82.7 million in 2003, compared with \$58.0 million in 2002. General and administrative expenses increased to \$27.6 million from \$18.4 million in 2003 and 2002, respectively. The increases reflect expenses related to expanded research activities following the Eos acquisition, expanded and larger-scale clinical trial activity, direct scale-up and manufacturing expenses and the additional headcount required to pursue our research and clinical development programs.

Total revenues during the three months ended December 31, 2003, were \$13.6 million, compared with \$10.7 million in the fourth quarter of 2002. Research and development expenses were \$24.4 million in the fourth quarter of 2003, compared with \$15.7 million in the same period of 2002. General and administrative expenses were \$8.1 million and \$5.2 million in the 2003 and 2002 fourth quarters, respectively. We reported a net loss of \$72.9 million, or \$0.78 per basic and diluted share, in the last three months of 2003, including non-GAAP adjustments, compared with a net loss of \$7.9 million, or \$0.09 per basic and diluted share, in the fourth quarter of 2002. Excluding non-GAAP adjustments of \$55.3 million, consisting primarily of acquired in-process research and development of \$48.2 million associated with the repurchase from Roche of rights to market and manufacture Zenapax in indications other than transplantation and \$6.5 million related to the fourth quarter redemption of its 5.50% Convertible Subordinated Notes with a principal amount of \$150 million, the non-GAAP net loss in the fourth quarter of 2003 would have been \$17.6 million, or \$0.19 per basic and diluted share.

Clinical Results Anticipated in 2004

Nuvion® (visilizumab, humanized anti-CD3). PDL continues to actively accrue patients into an ongoing Phase I/II trial of visilizumab in patients with severe ulcerative colitis whose disease has not responded to treatment with intravenous (I.V.) corticosteroids. This trial was initiated in the fourth quarter of 2003 based on a study designed to explore four dose levels of Nuvion 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, up to an additional 20 patients will be treated in the Phase II portion. We anticipate reporting preliminary results from the Phase I portion of the study in the second quarter of 2004.

Preliminary findings from a Phase I study of visilizumab in the same patient population were reported during the May 2003 Digestive Disease Week (DDW) meeting. A strong signal of activity in the Phase I trial was observed in the first dose cohort, given 15 µg/kg on days 1 and 2. A continued strong signal of activity has been subsequently observed in the second dose cohort given at 10 µg/kg given I.V. on days 1 and 2. To date, a total 10 of the 12 evaluable patients in the second dose cohort have responded to treatment with visilizumab, and 6 of 12 achieved remission. The visilizumab Phase I study is now closed to further enrollment with 32 patients enrolled. An abstract for this study has been accepted for presentation during the May 2004 DDW meeting. The Phase I and Phase I/II studies are currently anticipated to serve as the basis for discussions with regulatory agencies in the second half of 2004 regarding the design of possible registrational trials.

Daclizumab (Zenapax®, anti-IL-2R). 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. We anticipate that results from this trial will be available by the end of the

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second quarter of 2004. Preparatory work for a PDL study of daclizumab in multiple sclerosis continues. Results of an initial Phase II study of daclizumab in asthma will be reported in a poster presentation at the American Academy of Allergy, Asthma & Immunology (AAAAI) on March 23, 2004, in San Francisco.

HuZAF™ (fontolizumab, anti-gamma interferon). PDL is conducting two randomized, placebo-controlled, double-blind trials of HuZAF in Crohn's disease. The first study explores the effect of an initial I.V. dose of HuZAF given as 1 mg/kg or 4 mg/kg, followed by additional lower subcutaneous doses. In the second randomized, placebo-controlled, double-blind trial in Crohn's disease, patients receive up to two I.V. doses of HuZAF given at 4 mg/kg or 10 mg/kg. Both trials are now closed to further enrollment. The primary endpoint for both trials is the response to the initial I.V. dose. We expect to report results of both Phase II studies by the May 2004 DDW meeting.

M200 (anti-alpha5beta1 integrin antibody). We continue to enroll patients in a Phase I, dose-escalation study of M200, the 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.

Outlook

The following statements are based on expectations as of February 26, 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 two recently licensed Genentech antibody products, Xolair and Raptiva, and the timing of the possible approval and launch of Genentech's Avastin, anticipated in 2004. Excluding all non-GAAP adjustments, our guidance for 2004 compared to 2003 is as follows:

Revenues and Interest Income

For 2004, we expect that total revenues will increase by approximately 17-22% compared to total revenues in 2003, as a result of anticipated increases in royalties and license and other revenues. In addition, we expect interest income for the year to total approximately \$11 million to \$13 million.

Costs and Expenses

We anticipate that total costs and expenses will increase approximately 39-44% in 2004 compared with total costs and expenses in 2003. The increase in total costs and expenses is expected to be related primarily to expanded clinical trial activity, including associated direct scale-up and manufacturing expenses, and to the additional headcount required to pursue our clinical trial programs and to continue to expand our research, manufacturing and process

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development infrastructure. We expect a total of approximately 650-675 full-time personnel at year-end 2004.

Capital Expenditures and Cash Balances

We expect capital expenditures in the range of approximately \$100 million to \$110 million in 2004. Of these, approximately \$85 million to \$90 million are expected to be related to construction of our new manufacturing center at Brooklyn Park, Minn. If expended, these amounts will represent substantially all of the initially contemplated capital investment in our new manufacturing center.

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

Net Loss

We currently expect a net loss in 2004 in the range of approximately \$70 million to \$75 million, or approximately \$0.74 to \$0.79 per diluted share.

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its full-year and fourth quarter 2003 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 February 26. A replay of the conference call will also be available by telephone from approximately 6:30 p.m. Eastern time on February 26 through 6:30 p.m. Eastern time on March 1, 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 21186245.

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 depend in principal part on the total headcount of the organization as well as the timing of expenses. PDL revenues depend upon the success and timing of sales of our licensees and partners, including in particular the possible approval of and successful launch of Avastin antibody product from 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 is dependent upon 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, Phase II clinical studies of daclizumab and fontolizumab, and the Phase I study with M200 will be successful or completed on the anticipated schedules. Other factors that may cause

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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, 2002, in our Quarterly Report on Form 10-Q for the three months ended September 30, 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 U.S. trademark of Hoffmann-La Roche Inc. 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.

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

(In thousands, except per share data)

	Three months ended December 31,		Year ended December 31,	
	2003	2002	2003	2002
Revenues:				
Royalties	\$ 8,896	\$ 7,263	\$ 52,704	\$ 40,421
License and other	4,717	3,450	13,982	5,952
Total Revenues	13,613	10,713	66,686	46,373
Costs and expenses:				
Research and development	24,409	15,733	82,732	57,978
General and administrative	8,148	5,236	27,613	18,373
Acquired in-process research and development	48,159	—	85,993	—
Total costs and expenses	80,716	20,969	196,338	76,351
Operating loss	(67,103)	(10,256)	(129,652)	(29,978)
Interest income and other income, net	(3,320)	5,843	9,831	25,978
Interest expense	(2,424)	(2,090)	(9,770)	(9,146)
Impairment loss on investment	—	(1,366)	(150)	(1,366)
Loss before income taxes	(72,847)	(7,869)	(129,741)	(14,512)
Provision for income taxes	12	15	73	42
Net loss	\$ (72,859)	\$ (7,884)	\$ (129,814)	\$ (14,554)
Basic and diluted net loss per share	\$ (0.78)	\$ (0.09)	\$ (1.40)	\$ (0.16)
Shares used in computation of basic and diluted net loss per share:	93,764	89,063	92,478	88,865

CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

(in thousands)	December 31, 2003	December 31, 2002*
Cash, cash equivalents, marketable securities, and restricted investments	\$ 504,993	\$ 606,410
Total assets	742,030	717,818
Total stockholders' equity	448,331	544,766

*Derived from the December 31, 2002 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 acquired in-process research and development, 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. 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 ongoing expenses from 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 in evaluating the Company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)

	Three months ended December 31,			
	GAAP	2003 Adjustments	Non-GAAP	2002 GAAP
Revenues:				
Royalties	\$ 8,896		\$ 8,896	\$ 7,263
License and other	4,717		4,717	3,450
Total revenues	13,613		13,613	10,713
Costs and expenses:				
Research and development	24,409	(595)(1)	23,814	15,733
General and administrative	8,148	(14)(1)	8,134	5,236
Acquired in-process research and development	48,159	(48,159)(2)	—	—
Total costs and expenses	80,716	(48,768)	31,948	20,969
Operating loss	(67,103)	48,768	(18,335)	(10,256)
Interest income and other income, net	(3,320)	6,538(3)	3,218	5,843
Interest expense	(2,424)	—	(2,424)	(2,090)
Impairment loss on investment	—	—	—	(1,366)
Loss before income taxes	(72,847)	55,306	(17,541)	(7,869)
Provision for income taxes	12	—	12	15
Net loss	\$ (72,859)	\$ 55,306	\$ (17,553)	\$ (7,884)
Basic and diluted net loss per share	\$ (0.78)		\$ (0.19)	\$ (0.09)
Shares used in computation of basic and diluted net loss per share:	93,764		93,764	89,063

(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.

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

(3) To exclude the charges associated with the extinguishment of our \$150 million convertible debt due February 2007.

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 acquired in-process research and development, 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. 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 ongoing expenses from 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 in evaluating the Company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)

	Year ended December 31,			
	GAAP	2003 Adjustments	Non-GAAP	2002 GAAP
Revenues:				
Royalties	\$ 52,704		\$ 52,704	\$ 40,421
License and other	13,982		13,982	5,952
Total Revenues	66,686		66,686	46,373
Costs and expenses:				
Research and development	82,732	\$ (939)(1)	81,793	57,978
General and administrative	27,613	(278)(1)	27,335	18,373
Acquired in-process research and development	85,993	(85,993)(2)	—	—
Total costs and expenses	196,338	(87,210)	109,128	76,351
Operating loss	(129,652)	87,210	(42,442)	(29,978)

Interest income and other income, net	9,831	6,538(3)	16,369	25,978
Interest expense	(9,770)	—	(9,770)	(9,146)
Impairment loss on investment	(150)	150(4)	—	(1,366)
Loss before income taxes	(129,741)	93,898	(35,843)	(14,512)
Provision for income taxes	73	—	73	42
Net loss	\$ (129,814)	\$ 93,898	\$ (35,916)	\$ (14,554)
Basic and diluted net loss per share	\$ (1.40)		\$ (0.39)	\$ (0.16)
Shares used in computation of basic and diluted net loss per share:	92,478		92,478	88,865

(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.

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

(3) To exclude the charges associated with the extinguishment of our \$150 million convertible debt due February 2007.

(4) To exclude the impairment loss related to an equity investment.

The information in these press releases should be considered accurate only as of the date of the release. PDL has no intention of updating and specifically disclaims any duty to update the information in these press releases. These press releases may contain forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those in the forward-looking statements. Factors that may cause such differences are discussed in PDL's filings with the Securities and Exchange Commission.