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): **August 3, 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 Number)	(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 August 3, 2004, regarding the second quarter 2004 financial results of Protein Design Labs, Inc.

99.2 Transcript of conference call held on August 3, 2004

Exhibits 99.1 and 99.2 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 August 3, 2004, the Company issued a press release (the "Press Release") announcing the Company's financial results for the fiscal quarter ended June 30, 2004 (the "Results"). In conjunction with the issuance of the Press Release, the Company conducted a conference call on August 3, 2004 to discuss the Results with investors and financial analysts. Copies of the Press Release and transcript of 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.

The information furnished in this Item 12 and Exhibits 99.1 and 99.2 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: August 10, 2004

By: /s/ Glen Sato
Glen Sato
Senior Vice President
and Chief
Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated August 3, 2004, regarding the second quarter 2004 financial results of Protein Design Labs, Inc.
99.2	Transcript of conference call held on August 3, 2004.

www.pdl.com

For Immediate Release

Contact:

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

PROTEIN DESIGN LABS ANNOUNCES SECOND QUARTER 2004 FINANCIAL RESULTS

Revenue Guidance Revised Upward;
Anticipate 2004 Revenues of $88 to $91 Million

Fremont, Calif., August 3, 2004 – Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported a net loss of $12.5 million, or $0.13 per basic and diluted share, for the three months ended June 30, 2004, compared with a net loss of $42.1 million, or $0.45 per basic and diluted share, for the three months ended June 30, 2003. Excluding certain non-cash charges, the non-GAAP net loss in the second quarter of 2004 would have been $11.1 million, or $0.12 per basic and diluted share.

As of June 30, 2004, PDL had cash, cash equivalents, marketable securities and restricted investments totaling approximately $439.0 million, compared with $505.0 million at December 31, 2003. The June 30, 2004 balances reflected approximately $58.6 million in capital expenditures made during the first six months of 2004, primarily related to budgeted ongoing construction of PDL's manufacturing plant at Brooklyn Park, Minnesota.

PDL reported total revenues of $25.8 million in the second quarter of 2004, an increase of 23% over total revenues of $21.0 million in the same three months of 2003. The increase included a 38% increase in royalties, which totaled $24.7 million in the 2004 second quarter, compared with $17.9 million in the same three months of 2003. License and other revenues decreased from the prior-year period as a result of entering into fewer collaboration agreements in the current period.

Royalty revenues in the 2004 second 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 second quarter of 2004 compared to the same period in 2003 primarily were due to continued significant sales growth of both Herceptin and Synagis. Royalty revenues in the 2003 second quarter did not include royalties on Avastin, Xolair and RAPTIVA.

Protein Design Labs, Inc.
34801 Campus Drive
Fremont, CA 94555
Tel: 510.574.1400
Fax: 510.574.1500

Total costs and expenses were $39.5 million in the 2004 second quarter, compared with $65.6 million in the comparable three months of 2003, which included an acquired in-process research and development charge of $37.8 million associated with the April 2003 acquisition of Eos Biotechnology, Inc. 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, stock-based compensation charges, and charges related to the closure of our New Jersey operations, non-GAAP total costs and expenses in the 2004 second quarter would have been $38.1 million compared to $27.4 million for the comparable period in 2003.

Research and development expenses increased 56% to $32.0 million in the 2004 second quarter, compared with $20.5 million in the 2003 second quarter. The increase in research and development expenses reflected the growth in the company's clinical development pipeline; additional headcount required to pursue research and clinical development programs; expanded and larger-scale clinical trial activity; increased research activities; direct scale-up and manufacturing expenses; facility and equipment-related costs and contract manufacturing expense. General and administrative expenses increased to $7.5 million in the 2004 second quarter from $7.2 million in the 2003 second quarter.

Total revenues during the first six months of 2004 were $53.4 million, compared with $43.7 million in the first six months of 2003. Royalties in the first six months this year were $46.7 million, or 33% higher than the $35.0 million of royalties reported in the first half of 2003. Research and development expenses were $65.0 million in the first six months of 2004, compared with $36.5 million in the comparable six months of 2003. General and administrative expenses were $15.5 million and $12.5 million in the first six months of 2004 and 2003, respectively. PDL reported a net loss of $25.1 million, or $0.27 per basic and diluted share, for the first six months of 2004, compared to a net loss of $38.1 million, or $0.42 per basic and diluted share, in the first half of 2003 which included an acquired in-process research and development charge of $37.8 million and amortization of capitalized workforce associated with the Eos acquisition. Excluding certain non-cash charges, the non-GAAP net loss in the first six months of 2004 would have been $23.0 million, or $0.24 per basic and diluted share, compared to break-even results in the comparable period in 2003.

Second Quarter 2004 Clinical Development Highlights

Nuvion® Antibody Product (visilizumab, humanized anti-CD3). Results from the 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 May 2004. A strong signal of activity in the Phase I trial 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.

Accrual continues into all dose levels in the Phase I/II trial evaluating visilizumab in patients with severe ulcerative colitis refractory to intravenous steroids. This 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. Currently, 50 patients have been treated in this study. Patients with undetectable Epstein-Barr Virus (EBV) levels are randomized into treatment in one of the four dose levels. Patients with detectable EBV, but counts less than 5,000 copies/ml have been enrolled in successive cohorts, beginning with the lowest dose level. Currently patients with detectable EBV are being enrolled in the 10 µg/kg dose level. Following the Phase I portion of the study, PDL plans to treat up to an additional 20 patients in the Phase II portion.

An abstract of this study has been accepted for presentation during the 12th United European Gastroenterology Week (UEGW) meeting in Prague, Czech Republic, on September 29, 2004. The presentation will describe the safety and activity of visilizumab observed in the Phase I portion of the trial.

Currently, we anticipate that the completed 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.

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 FEV_1 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 FEV_1 of 4.4% of baseline, compared to placebo patients who experienced a mean decrease of 1.5% (p=0.05). Treatment with daclizumab was generally well tolerated. The overall frequency and severity of adverse events did not differ between daclizumab and placebo groups. PDL is actively reviewing further development options and currently expects that the next trial of daclizumab in asthma will involve subcutaneous administration. An update on further clinical plans is planned around the beginning of the fourth quarter of 2004.

In May 2004, PDL reported results from a Phase II clinical study of daclizumab in patients with moderate-to-severe ulcerative colitis. Daclizumab did not meet primary or secondary endpoints in the trial, and we do not intend to develop it further for this indication. Preparatory work for a PDL study of daclizumab in multiple sclerosis continues.

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 in pancreatic cancer, non-small cell lung cancer and melanoma in combination with chemotherapy. An abstract of the Phase I study has been accepted as a poster presentation on September 29, 2004, at the 16th EORTC-NCI-AACR symposium on Molecular Targets and Cancer Therapeutics in Geneva, Switzerland.

F200 (anti-alpha5beta1 integrin antibody fragment). Our related preclinical candidate antibody, F200, a single-chain antibody targeting alpha5beta1 integrin, is progressing toward a late 2005 IND application, for the potential treatment of age-related

macular degeneration. In addition, promising molecules continue to emerge from our antibody discovery efforts, and we plan to present several of our newest programs as part of an overall R&D discussion we expect to host in New York City in the fourth quarter of 2004.

Outlook

The following statements are based on expectations as of August 3, 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 operating 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 have updated our financial guidance for 2004 compared to 2003, originally provided in February 2004, with expectations compared to December 31, 2003 non-GAAP performance as follows: (a) total revenues will increase by approximately 32-37% (previously 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 $9 million to $11 million; (c) total costs and expenses increasing by approximately 37-42% (previously 39-44%) in 2004 compared with total costs and expenses in 2003; and capital expenditures in the range of approximately $100 million to $105 million in 2004 (previously $100 million to $110 million). Of these anticipated capital expenditures, 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 expect a net loss in 2004 in the range of approximately $60 million to $65 million (previously $70 million to $75 million), or approximately $0.64 to $0.69 (previously $0.74 to $0.79) 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.

Finally, we anticipate having available cash, cash equivalents, marketable securities and restricted investments of approximately $360 million at the end of 2004.

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its second 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 August 3. A replay of the conference call will also be available by telephone from approximately 6:30 p.m. Eastern time on August 3 through 6:30 p.m. Eastern time on August 6, 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 21200376.

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 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 March 31, 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 June 30, 2004	Three months ended June 30, 2003	Six months ended June 30, 2004	Six months ended June 30, 2003
Revenues:				
Royalties	$ 24,731	$ 17,905	$ 46,741	$ 35,050
License and other	1,052	3,096	6,670	8,698
Total revenues	25,783	21,001	53,411	43,748
Costs and expenses:				
Research and development	32,009	20,538	65,038	36,511
General and administrative	7,450	7,193	15,518	12,502
Acquired in-process research and development	—	37,834	—	37,834
Total costs and expenses	39,459	65,565	80,556	86,847
Operating loss	(13,676)	(44,564)	(27,145)	(43,099)
Interest and other income, net	2,583	4,188	4,867	8,861
Interest expense	(1,351)	(1,755)	(2,736)	(3,641)
Impairment loss on investment	—	—	—	(150)
Loss before income taxes	(12,444)	(42,131)	(25,014)	(38,029)
Provision for income taxes	8	18	56	49
Net loss	$ (12,452)	$ (42,149)	$ (25,070)	$ (38,078)
Net loss per basic and diluted share:	$ (0.13)	$ (0.45)	$ (0.27)	$ (0.42)

Shares used in computation of net loss per basic and diluted share:	94,587	93,301	94,294	91,242

CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

(In thousands)	June 30, 2004	December 31, 2003* (unaudited)
Cash, cash equivalents, marketable securities and restricted investments	$ 439,013	$ 504,993
Total assets	721,588	742,030
Total stockholders' equity	433,454	448,331

*Derived from the December 31, 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.

	Three months ended June 30,					
	2004			2003		
(In thousands, except per share data)	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Royalties	$ 24,731		$ 24,731	$ 17,905		$ 17,905
License and other	1,052		1,052	3,096		3,096
Total revenues	25,783		25,783	21,001		21,001
Costs and expenses:						
Research and development	32,009	(1,377)(1)	30,632	20,538	(361)(2)	20,177
General and administrative	7,450	(14)(1)	7,436	7,193	(14)(2)	7,179
Acquired in-process research and development	—		—	37,834	(37,834)(3)	—
Total costs and expenses	39,459	(1,391)	38,068	65,565	(38,209)	27,356
Operating loss	(13,676)	1,391	(12,285)	(44,564)	38,209	(6,355)
Interest and other income, net	2,583		2,583	4,188		4,188
Interest expense	(1,351)		(1,351)	(1,755)		(1,755)
Impairment loss on investment	—		—	—		—
Loss before income taxes	(12,444)	1,391	(11,053)	(42,131)	38,209	(3,922)
Provision for income taxes	8		8	18		18
Net loss	$ (12,452)	$ 1,391	$ (11,061)	$ (42,149)	$ 38,209	$ (3,940)
Net loss per basic and diluted share:	$ (0.13)		$ (0.12)	$ (0.45)		$ (0.04)
Shares used in computation of net loss per basic and diluted share:	94,587		94,587	93,301		93,301

(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.

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.

	Six months ended June 30,					
	2004			2003		
(In thousands, except per share data)	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Royalties	$ 46,741		$ 46,741	$ 35,050		$ 35,050
License and other	6,670		6,670	8,698		8,698
Total revenues	53,411		53,411	43,748		43,748
Costs and expenses:						
Research and development	65,038	(1,995)(1)	63,043	36,511	(361)(2)	36,150
General and administrative	15,518	(28)(1)	15,490	12,502	(14)(2)	12,488
Acquired in-process research and development	—		—	37,834	(37,834)(3)	—
Total costs and expenses	80,556	(2,023)	78,533	86,847	(38,209)	48,638
Operating loss	(27,145)	2,023	(25,122)	(43,099)	38,209	(4,890)
Interest and other income, net	4,867		4,867	8,861		8,861
Interest expense	(2,736)		(2,736)	(3,641)		(3,641)
Impairment loss on investment	—		—	(150)		(150)
Income (loss) before income taxes	(25,014)	2,023	(22,991)	(38,029)	38,209	180
Provision for income taxes	56		56	49		49
Net income (loss)	$ (25,070)	$ 2,023	$ (23,047)	$ (38,078)	$ 38,209	$ 131
Net income (loss) per share:						
Basic	$ (0.27)		$ (0.24)	$ (0.42)		$ 0.00
Diluted	$ (0.27)		$ (0.24)	$ (0.42)		$ 0.00
Shares used in computation of net income (loss) per share:						
Basic	94,294		94,294	91,242		91,242
Diluted	94,294		94,294	91,242		92,605

(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.

Conference Call Transcript

PDLI Q2 2004 Protein Design Earnings Conference Call

Event Date/Time: Aug. 03. 2004 / 4:30PM ET
Event Duration: N/A

CORPORATE PARTICIPANTS

Jim Goff
Protein Design Labs - Senior Dir. of Corp. Communications

Mark McDade
Protein Design Labs - CEO

Glen Sato
Protein Design Labs - CFO

Dr. Steven Benner
Protein Design Labs - Chief Medical Officer

CONFERENCE CALL PARTICIPANTS

Paul Wagner
Lehman Brothers - - Analyst

Matthew Geller
CIBC - Analyst

Joel Sendek
Lazard - Analyst

Charles Duncan
JMP Securities - - Analyst

Phil Nadeau
SG Cowen - Analyst

Elise Wang
Smith Barney Citigroup - Analyst

Gabe Hoffman
Asset Capital Management - Analyst

Hui Shao
Mehta Partners - - Analyst

Greg Wade
Pacific Growth Equities - Analyst

Ron Ellis
Leerink Swann - Analyst

PRESENTATION

Operator

Welcome to the Protein Design Lab's second-quarter 2004 financial results conference call. During the presentation all participants will be in a listen-only mode. Afterwards we will conduct a question-and-answer session. (OPERATOR INSTRUCTIONS) As a reminder, this conference is being recorded Tuesday, August 3, 2004. I would now like to turn the conference over to Mr. Jim Goff, Senior Director of Corporate Communications.

Jim Goff - ***Protein Design Labs*** - ***Senior Dir. of Corp. Communications***

Good afternoon, everyone, and thank you for joining Protein Design Lab's first-quarter 2004 conference call. With me today are Mark McDade, our Chief Executive Officer; Glen Sato, Chief Financial Officer; and Dr. Steven Benner, our Chief Medical Officer. As we begin I remind you that the material we will cover includes forward-looking statements that involve risks and uncertainties; in particular those statements in which we discuss our expectations, plans and beliefs.

Actual results could be materially different from what we currently expect. In particular our results could be affected by, "A", the timing of expenses in particular related to clinical trials and manufacturing; "B", the success and timing of sales of our licensees and partners including in particular the continued successful launch of Avastin antibody product from Genentech as well as the seasonality of sales of Synagis from MedImmune Inc.; "C", the timing of and, if at all, our ability to enter into new, if any, collaborative humanization and patent licensing agreements; "D", our ability to enforce and protect our patents either through entry into licensing agreements or otherwise which in significant part depends upon the scope and validity of our intellectual property rights; and "E", in particular with respect to clinical development expectations, our ability to initiate planned trials as currently anticipated and whether the results from those trials will be successful or achieved by the currently anticipated dates.

In addition we refer you to the risk factor sections in our current 10-K and 10-Q reports and other SEC filings for information about those risks. As a preliminary note, the differences in non-GAAP and GAAP results are reconciled in our financial press release, and any material non-GAAP financial information discussed on the call and not otherwise contained in our press release will be reconciled to corresponding or comparable GAAP financial information on our website, that's at www.PDL.com in the news section.

At this time let me introduce the remainder of the call with Mark McDade, our Chief Executive Officer, who has introductory

remarks. Chief Financial Officer Glen Sato will review second-quarter financial results, and our Chief Medical Officer, Dr. Steven Benner, will provide a clinical update for the quarter. Here's Mark.

Mark McDade - ***Protein Design Labs*** - ***CEO***

Thank you, Jim. As you will hear from Glen and Steve in more detail, we've had a very productive and encouraging first half of 2004. Financially this progress is thanks to the success of our partners, most notably Genentech and MedImmune, in their marketing efforts supporting existing therapies like Herceptin and Synagis antibody products or in launching new antibody therapies such as Xolair, Raptiva and Avastin.

We are pleased to guide higher than previously anticipated royalty revenues for the full year 2004 on a sizable year-over-year growth for first-half 2004 compared to first-half 2003. As well, the PDL team is managing our business carefully as evidenced by the fact that we're guiding down slightly in operating expenses even as we move forward with several clinical programs and remain on track to achieve our 2004 goals.

In development a mix of success and failure over the past 6 months typical of a biopharmaceutical company with a portfolio of clinical stage opportunities has enabled us to forge ahead with 3 clear clinical priorities. "A", Nuvion for severe ulcerative colitis refractory to intravenous steroids; "B", daclizumab for asthma; and "C", M200 for potential treatment of solid tumors. Our top business priority, apart of course from carefully managing PDL, is to partner daclizumab in asthma by the end of this year. I believe we're on track to achieve this objective.

A partnership should enable PDL to optimize product development in a major disease in the U.S. and gain significant resource flexibility to apply to our other priority programs without necessarily consuming increasingly larger cash amounts year after year. We've continued to strengthen our team at PDL, though the hiring pace as clearly slowed compared to last year. And I'm pleased to welcome Dr. Max Link as our new Chairman, only the second in our history as a public company. His background as a seasoned pharmaceutical executive should serve us well as we continue on our path to marketing our own drugs in North America by 2007.

Before I turn the call over to Glen and Steve for more details on our results for the quarter, let me extend my thanks to the PDL team including our clinical advisers and investigators for an excellent and productive first half. And my thanks to the analyst and investment community for your interest and support. I'm looking forward, therefore, to an exciting and equally productive second half of 2004. Now let me turn the call over to Glen Sato to review our second-quarter results.

Glen Sato - ***Protein Design Labs*** - ***CFO***

Thank you, Mark. As Mark noted, we feel very, very good about our business. We had a very productive second quarter highlighted by a number of important events related to both our increasing royalty stream and some successful results from our product development pipeline. As you know, during the quarter we began to receive royalties on Avastin sales from Genentech and Xolair appears to have a promising start as its first full year of launch continues. Consequently our second-quarter results continue to demonstrate our ability to run the business and maintain a strong financial position.

As of June 30, 2004 our cash, cash equivalents, marketable securities and restricted investments totaled $439 million compared with $505 million at year end 2003. The June 30, 2004 balances reflect capital expenditures of $58.6 million made in the first 6 months most of which related to the construction of our new manufacturing plant at Brooklyn Park, Minnesota.

Focusing now on our second-quarter operating results; we reported $25.8 million in total revenues for the second quarter of 2004. Topline growth of 23 percent in the second quarter compared to the prior year quarter was again driven by strong growth in royalty revenues under licenses to PDL's humanization patents. Royalties in the second quarter of 2004 totaled $24.7 million, a 38 percent increase over royalties of $17.9 million in the second quarter of 2003. Royalty growth was driven by continued strong sales of both Herceptin and Synagis as well as the addition of royalties on 3 recently licensed products,

Avastin, Xolair, and Raptiva. License and other revenues for the period were lower, $1 million compared to $3.1 million in the comparable period last year as we entered into fewer collaboration agreements in the current period compared to the prior period of 2003.

Turning to the expense side, research and development expenses totaled $32 million for the 2004 second quarter compared with $20.5 million in the 2003 second quarter. The increase in R&D reflects growth in our clinical pipeline, additional headcount required to pursue research and clinical development programs, expanded and larger scale clinical trial activity, increased research activities, direct scale-up and manufacturing expenses, facility and equipment related costs and contract manufacturing expense.

R&D expenses in the 2004 second quarter also included about $288,000 related to the closure of our New Jersey satellite clinical office. As part of a strategic initiative to centralize our U.S. clinical operations efforts and to improve our efficiency and productivity in the oversight of clinical trials, in June 2004 we approved a plan pursuant to which we closed the New Jersey office which was principally responsible for the oversight of certain clinical trials. The plan was a combination of a reduction in workforce of 9 employees and the abandonment of our New Jersey leased office facility.

General and administrative expenses were essentially flat at $7.5 million in the quarter compared to $7.2 million in the second quarter of 2003. Overall our net loss for the second quarter of 2004 was $12.5 million or 13 cents per basic and diluted share compared with a net loss of $42.1 million or 45 cents per basic and diluted share in the second quarter a year ago. Excluding certain non-cash and other non-recurring charges in the second quarter of 2004, our non-GAAP net loss for the second quarter was $11.1 million or 12 cents per basic and diluted share compared to a non-GAAP net loss of $3.9 million or 4 cents per basic and diluted share in the same period last year.

For the 6 months ending June 30, 2004 total revenues during the period were $53.4 million compared to $43.7 million in the first 6 months of 2003. Royalties in the first 6 months of this year were $46.7 million compared to $35 million of royalties reported in the first half of 2003. License and other revenue were $6.7 million and $8.7 million for the first 6 months of 2004 and 2003, respectively. Research and development expenses were $65 million in the first 6 months of 2004 compared with 36.5 million in the comparable 6 months of 2003. General and administrative expenses were $15.5 million and $12.5 million in the first 6 months of 2004 and 2003, respectively.

PDL reported a net loss of $25.1 million or 27 cents per basic and diluted share for the first 6 months of 2004 compared to a net loss of $38.1 million or 42 cents per basic and diluted share in the first half of 2003, which included an acquired in-process research and development charge of $37.8 million and amortization of capitalized workforce associated with our acquisition of Eos Biotechnology. Excluding certain non-cash and non-recurring charges, the non-GAAP net loss in the first 6 months of 2004 would have been $23 million or 24 cents per basic and diluted share compared to breakeven results in the comparable period in 2003.

We have today updated our financial guidance for the remainder of 2004 compared to December 31, 2003 non-GAAP financial performance. We remind you that our results are substantially dependent on royalty revenues from our licensees and the timing of entry into new collaborative arrangements. For the remainder of 2004 we will not offer guidance on a quarterly basis as increases in our revenues will be dependent on the continued success of licensed antibody products including 3 recently launched Genentech products: Xolair, Raptiva and Avastin. We do expect to provide quarterly guidance beginning in 2005.

Let me now turn to our revised guidance. I'm pleased to point out that our revenue guidance for 2004 is being raised on the basis of very strong performance by licensed products, Genentech's Avastin in particular. Our revised 2004 guidance as compared to our guidance provided at the beginning of the year is as follows: total revenues increasing by approximately 32 to 37 percent compared to total revenues in 2003; interest income for the year to total approximately $9 to $11 million; total costs and expenses increasing by approximately 37 to 42 percent in 2004 compared with total costs and expenses in 2003; and capital expenditures in the range of $100 million to $105 million in 2004 of which approximately $85 to $90 million are expected to be related to construction of our new manufacturing center at Brooklyn Park, Minnesota. These amounts continue to represent substantially all of the initially contemplated capital investment in our new manufacturing center which remains on track in terms of budget and timeline.

As a result of this revised guidance we expect a net loss in 2004 in the range of approximately $60 million to $65 million or approximately 64 to 69 cents per basic and diluted share. I want to note that this is a reduced loss of probably about approximately 10 cents per share; we're very excited about our financial performance through the remainder of the year. We continue to expect total full-time employee headcounts to be in the range of 650 to 675 employees at year end 2004.

Finally, we anticipate having available cash, cash equivalents, marketable securities and restricted investments of approximately $360 million at year end 2004. I want to emphasize that our results will likely change favorably from this guidance in the event that we complete a product partnership for daclizumab or any other similar collaboration.

As an additional comment I want to mention all but one of our executive officers and 2 directors during the second quarter adopted trading plans under Rule 10b5-1 of the Securities Exchange Act. These trading plans specify the trading period, the number of shares of common stock to be sold, and prices and conditions under which shares held by directors, officers and employees may be sold. Under the plans an independent broker executes the trades pursuant to the specific selling instructions provided by the relevant individual at the time the plan is originally established. We expect to disclose additional detail regarding trading plans in the second-quarter 10-Q. I will respond to further questions in this regard during the Q&A portion of today's call. Let me at this time turn the call over to our Chief Medical Officer, Dr. Steven Benner, for additional comments.

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

As most of you know, Nuvion, or visilizumab, our anti-CD3 antibody, is PDL's highest clinical development priority. At the May Digestive Disease Week meeting, Dr. Scott Plevy reported on the results of a 32-patient Phase I clinical trial of visilizumab in patients with severe ulcerative colitis who had not responded to treatment with intravenous steroids. Dr. Plevy reported a strong signal of activity in that Phase I trial — where the first dose was administered at a dose of 15 micrograms per kilogram on days 1 and 2 and in which all 8 patients achieved remission.

Dr. Plevy additionally reported that we've continued to observe a strong signal of activity in the second dose cohort, 10 micrograms per kilogram IV, again on days 1 and 2. At this dose level 19 of 24 patients responded to treatment and 13 achieved remission. PDL is actively accruing patients into an ongoing Phase I/II trial of visilizumab in severe ulcerative colitis as we continue to explore a range of lower doses.

There are 3 treatment components to this trial. The primary goal of the trial is to establish the optimal dose of visilizumab for the use in registrational trials. This will be accomplished through the Phase I dose ranging component of the trial. When the Phase I portion of the trial is completed, an additional 20 patients will be enrolled in the Phase II portion of the study. This component of the study is designed to give us additional experience with visilizumab at the optimal dose level. Patients enrolled in the Phase II portion of the study will be receiving their initial dose of visilizumab.

The third exploratory component of this ongoing study is an option for retreatment. Patients previously treated with visilizumab in the completed Phase I trial or in the ongoing study who achieve a response, Modified Truelove Witts Severity Index score of less than 10, and later relapse within 1 year could receive 1 additional course of visilizumab. The retreatment component does not influence the conduct or the interpretation of the Phase I/II trial. The Phase I/II trial was initiated in the fourth quarter of 2003 and was designed to explore 4 dose levels of Nuvion, from 5 micrograms per kilogram to 12.5 micrograms per kilogram IV on days 1 and 2 as a bolus injection. This phase is targeted to enroll up to 80 patients, approximately 20 per dose level.

Following the Phase I portion of the study, we plan to treat up to an additional 20 patients in the Phase II portion. The Phase II portion of the trial is expected to begin by the first quarter of next year following completion of the Phase I component.

Accrual continues into all doses in the Phase I dose ranging component of this Phase I/II trial evaluating visilizumab in patients with severe ulcerative colitis refractory to intravenous steroids. Currently 50 patients have been treated in this part of the study. Patients with undetectable Epstein-Barr virus, EBV levels are randomized into treatment at any one of the 4 dose levels. Patients with detectable EBV, but counts less than 5,000 copies per milliliter, have been enrolled in successive cohorts beginning with the lowest dose level. Patients with detectable EBV have been enrolled in the 10 microgram per kilogram dose cohort filling — the cohort. We now anticipate that the next patients with detectable EBV will be enrolled in the 12.5 microgram per kilogram dose level.

We've been pleased with the safety profile observed to date in this ongoing study in both the EBV positive and EBV undetectable patients. We've continued to observe the activity of Nuvion in this dose setting at all the dose levels tested. In addition, as I explained, this protocol includes an option for retreatment of patients enrolled in this study or in the previously completed Phase I trial. I'd like to again emphasize, however, that this portion of the study is optional and originally contemplated as exploratory in nature and is separate from both the Phase I portion and the Phase II portion.

The option for retreatment is available for patients who achieved a response to their initial course of visilizumab but subsequently relapsed. Patients are retreated with the same dose of visilizumab that they originally received. In this optional retreatment portion to date 4 patients have received a second course of visilizumab. All 4 of these patients had been participants in the completed Phase I trial who were previously treated with 10 micrograms per kilogram. Among these 4 patients, 2 met the protocol defined criteria for a dose limiting toxicity or DLT. One DLT was the slow recovery of the CD3 positive CD4 positive T-cell count at day 60. The most recent assessment of this count revealed a count of 175 cells per microliter at day 90 compared to the screening level of CD3/CD4 positive T-cells of 218 cells per microliter. The patient has had no apparent complications associated with this period of T-cell suppression.

The second patient reported having a DLT had an asymptomatic elevation in Epstein-Barr virus levels. This patient had been treated with 6-mercapta purine just prior to visilizumab retreatment and had a CD3 positive/CD4 positive T-cell count of 49 cells per microliter prior to the visilizumab retreatment. The DLT was a delay in decline following the expected rise in Epstein-Barr virus levels. In this case EBV increased to 15,310 copies per milliliter on day 60, subsequently on day 70 EBV levels had declined to 1,409 copies per milliliter and they were again undetectable by day 87.

Per protocol, these cases have been forwarded to an independent Data and Safety Monitoring Board or DSMB. Pending DSMB review, additional patients will not be enrolled in the optional retreatment phase of the study. PDL expects that the retreatment phase of the study will resume enrolling patients after the DSMB review of these cases. A response from the DSMB is expected in less than 2 weeks.

While we have seen a couple of DLT's, which is to be expected in this early stage of testing, we have also seen activity in the retreated patients. Since we do not see the DSMB meeting as significant to our timelines and expect the DSMB to agree with continuing accrual in the exploratory retreatment phase of the study, we do not plan to provide an update following that meeting unless there is an impact on the ongoing Phase 1/2 trial or on our registrational plans. The observation of these DLT's does not alter the company's projected timeline for the development or the potential competitive positioning of visilizumab.

Again, I would like to stress that we do not currently believe these results will have a detrimental effect on our ongoing efforts. As noted above these patients were not treated under the Phase 2 portion of our study which is not expected to begin enrolling patients until the first quarter of 2005. Further, there have

been no other complications reported in these patients. Our aim for the ongoing dose-ranging study has been consistently to push ahead with an acute induction of remission indication for Nuvion in this severely ill patient population.

We remain on track with our strategy that focuses on the most rapid time to approval and we certainly plan related additional studies to support broader use once we have achieved approval to market this drug. We are pleased to report that an abstract of the study has been accepted for presentation during the 12th United European Gastroenterology Week meeting, the UEGW, in Prague, the Czech Republic on September 29, 2004. This presentation will describe the safety and activity of visilizumab observed in the Phase I portion of the trial and will also include an update on the findings in the retreatment phase.

In early trials visilizumab has shown a very high degree of activity in patients with severe ulcerative colitis that has not responded to 5 days of IV steroids. There are no approved medical interventions for these patients and their treatment alternatives are colectomy or experimental or off-label systemic treatments. The activity of visilizumab in this patient population coupled with what we believe is a manageable safety profile make visilizumab an exceptionally promising agent for the treatment of severe ulcerative colitis. We continue to anticipate that the Phase I trial and the Phase I portion of the ongoing study may serve as the basis for discussions with U.S. and European regulatory agencies in late 2004 regarding the design of possible registrational trials which are expected to begin in the first quarter of '05.

Turning now to our second development priority, daclizumab in asthma. In March we were very pleased to report positive results from the initial clinical study of daclizumab in patients with chronic persistent asthma whose disease was not well controlled with high doses of inhaled corticoid steroids. The primary endpoint, percent change in forced expiratory volume in 1 second, or FEV1, from baseline to 12 weeks met statistical significance with a P value of 0.05. Multiple secondary clinical end points also supported these findings.

This Phase II randomized double-blind placebo-controlled 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 percent of baseline compared to placebo patients who experienced a mean decrease of 1.5 percent. Treatment with daclizumab was generally well tolerated. The overall frequency and severity of adverse events did not differ between daclizumab and the placebo groups.

We currently expect that the next trial of daclizumab in asthma will be a follow-on trial in which daclizumab will be administered subcutaneously and we are currently working closely with a number of investigators to design our next trial. We've submitted an abstract requesting presentation at this fall's American College of Asthma, Allergy and Immunology meeting, the ACAAI meeting in Boston, and hope to provide a more complete data set pertaining to subset analyses of the first treatment period as well as the second treatment period results as part of that presentation. We are very encouraged by the additional data we have gleaned from the Phase II study.

I should also mention that we continue on schedule to initiate a follow-on study in multiple sclerosis in the first quarter of 2005. I'm pleased to report that enrollment is going very well in our Phase I dose escalation study of M200, our anti-alpha 5 beta 1 integrin antibody. This anti-angiogenic antibody targets the endothelium of tumor neovasculature and is being developed as a treatment for solid tumors. We plan to present Phase I data at the end of this quarter and remain on track to initiate a series of Phase II trials in multiple solid tumors beginning late this year.

Our fourth clinical program is HuZAF, or fontolizumab, our humanized anti-gamma interferon antibody. In March PDL reported the results of two randomized placebo-controlled double-blind trials of HuZAF in Crohn's disease. The primary endpoint for both trials was response to an initial IV dose. PDL reported that HuZAF did not meet the primary endpoint in either trial following the administration of a single intravenous dose. We did, however, in a subset analysis of CRP-elevated patients identify a very strong signal of activity. Given the recent success of our pipeline and the allocation of resources to higher priority programs, we're currently seeking a partner for HuZAF before initiating additional development in Crohn's disease.

Our lead preclinical candidate, F200, is progressing well and we expect to be able to enter the clinic with this antibody fragment in late 2005. To summarize then PDL's current development priorities and near-term milestones include: for Nuvion we will present the Phase I data from the current Phase I/II trial on September 29th at the United European Gastroenterology Week meeting in Prague; we anticipate discussions with the FDA regarding the design of potential registrational trials by the end of this year and, with a favorable outcome from these discussions, we hope to start the potential registrational trials in the first quarter of 2005; for Daclizumab we have submitted an abstract for presentation at the upcoming ACAAI meeting in Boston, we'll plan to begin a follow-on study in asthma in the fourth quarter of this year; and for M200 we will be presenting Phase I data in Geneva in late September at the EORTC-NCI-AACR meeting and expect to begin Phase II studies in combination with chemotherapy by the end of 2004. I would now like to return the call to Jim Goff.

Jim Goff - ***Protein Design Labs*** - ***Senior Dir. of Corp. Communications***

Thank you, Steve. That concludes our prepared presentations. Operator, at this time could we begin the Q&A?

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS) Paul Wagner, Lehman Brothers.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

Thank you for the clarity on the Nuvion trial. I do have a few questions around that. Steve, I know you said that for the patient with the dose limiting toxicity of an elevated EBV count, they weren't symptomatic. Was there any other sequelae associated with the elevated EBV count?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

No.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

And other than that elevated EBV count, were there any other notable infectious toxicities that may not have risen to level of a DLT that would spark a DSMB review?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

No.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

Great. And will you be announcing the DSMB outcome?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

As I said, we don't intend to announce the findings from the DSMB unless it changes the conduct of the Phase I/II trial or impacts on our registrational plan.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

Great. And then just one last question on Nuvion here. If I'm recalling correctly, there were 8 patients from that Phase I trial that had relapsed; so 4 of those were enrolled for retreatment. And I'm wondering, for the 4 that didn't enroll for retreatment, was there anything specific about those patients that prevented them from enrolling either EBV blood copy numbers or T-cell count recovery that prevented them from enrolling?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

It's a little bit more complicated than that. Initially for the Phase I study we enrolled 32 patients. We did not have an open retreatment option until the second trial, the ongoing Phase I/II study was open. So we lost an opportunity to retreat some patients that had failed during that interval.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

I see, thank you. And so just to clarify also, the registrational trial Phase III, that will be for induction only, there will be no retreatment component to that Phase III trial?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

We certainly anticipate that our initial indication will be to pursue an induction — a label. We are currently, as you'd imagine, under active discussions internally and with our advisors about including an option for retreatment either as a part of those trials or as an add on protocol, but we would not — so while that's likely to be part of a late stage development we would not anticipate that would be part of the initial label.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

Thanks. And then just a quick question on the market research study you presented. I think you've talked about 20,000 to 30,000 UC colectomies and I was wondering if you would clarify that number? Is that the number of patients in the severe population who over the course of their disease become steroid refractory and then require surgery or is that an annual number of colectomies?

Mark McDade - ***Protein Design Labs*** - ***CEO***

This is Mark. I believe that number reflects data that we've gathered from the Crohn's and Colitis Foundation and several other sources as to the total ulcerative colitis related colectomies performed on an annual basis. So they may or may not have been treated in some form. They may have gone straight to surgery, Paul, if that answers the question.

Paul Wagner - ***Lehman Brothers*** - ***Analyst***

Perfect, thank you very much.

Operator

Matthew Geller, CIBC.

Matthew Geller - - ***CIBC*** - ***Analyst***

A couple of questions on each of the products. On Nuvion, if you could just go into a little bit more detail about your source of confidence that you think the trials will continue with the second dosage of the drug? With daclizumab can you talk a little bit about your progress with partnerships with daclizumab and when might we see the first efficacy oriented data for M200?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

First, with regards to Nuvion. As I said, we are confident that following DSMB review that we'll be allowed to continue retreatment. The hold was based purely on the design of the protocol. As an early study it's designed for safety. So if it follows a cautious course as described in the protocol, but there's nothing specific that's really abnormal. We're confident that we'll be allowed to retreat patients and I want to reemphasize that the remainder of the trial is open and we continue to actively treat both EBV positive and EBV negative patients at all dose levels.

With regards to M200, we'll report at the NCI-EORTC meeting the findings including any evidence of activity for M200 as you'd expect in a safety trial of heavily pre-treated patients. The real goals of this are to define an optimal regimen with regards to pharmacokinetics and surrogate markers including monocyte saturation. The next trial that would really give us a much better picture of efficacy will be the Phase II trials that will start for the initial of those trials beginning in the fourth quarter of this year and those trials will probably run somewhere over — a little bit over a year.

Mark McDade - ***Protein Design Labs*** - ***CEO***

Let me answer the third question with respect to the daclizumab partnership. We feel confident that we will achieve that goal. Obviously nothing is set until you actually sign an agreement, but we continue to feel confident that we will achieve a dac partnership before year-end as we had originally contemplated on the last call.

Matthew Geller - - ***CIBC*** - ***Analyst***

Great. Thanks a lot.

Operator

Joel Sendek, Lazard.

Joel Sendek - ***Lazard*** - ***Analyst***

So the real risk here is that the retreatment portion of the Nuvion trial may be soft. So you don't see — just to kind of put you on the spot here — you don't see any risk that the Phase I or the Phase II or the Phase I/II on the current trial would be stopped?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

No, Joel, those are actually continuing to accrue patients and they're not being reviewed by the DSMB. The DSMB review is only for the retreatment phase, it's pro forma based on the definitions and the toxicities. As you know, both of those events were laboratory events that were asymptomatic. So we're optimistic that that will be allowed to be continued as well.

Joel Sendek - ***Lazard*** - ***Analyst***

Thanks for that clarification and sorry to prolong the agony. And then, Glen, can you give us a better feel for — actually I'm looking at my old notes. It seemed to me that I had an estimate of fewer patients, only maybe about 50 that I was expecting into the Phase I/II portion. Did you increase that to 80 or were my notes wrong?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

I think that's been consistently up to 80 patients depending on how many we need of both EBV positive and EBV negative patients whether or not toxicities are observed. It will be somewhere between the current 50 and 80 patients I would expect when that phase is completed. What's really driving the completion or the timing to completion of that phase of the study is our need to dose escalate through the series of EBV positive cohort. As I've told you, we've just put the final patient into the 10 microgram per kilogram cohort; when that patient is followed and does well then we'll be enrolling patients in the final 12.5 microgram per kilogram cohort. So we hope to begin that fairly soon.

Joel Sendek - ***Lazard*** - ***Analyst***

Great. And I guess a follow-on to that would be when's your best guess as to when the Phase II portion would start?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

We said today maybe in the first quarter, it could be earlier than that depending on how many patients we need to round out the final cohorts. But I want to be clear that that Phase II portion is not on a critical path in terms of our having discussions with either the FDA or our timing for the start of the registrational trial.

Joel Sendek - ***Lazard*** - ***Analyst***

So that's important to the Phase III — or the registration trial might start before you're done with Phase II portion?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

They could be overlapping and what I would anticipate is that as we get the Phase III studies up and running we'll roll sites into the new Phase III study.

Joel Sendek - ***Lazard*** - ***Analyst***

Okay, thank you.

Operator

Charles Duncan, JMP Securities.

Charles Duncan - - ***JMP Securities*** - ***Analyst***

First of all, congratulations on a great quarter. Secondly, this is a question aimed at Steve. Steve, as I recall when you initially presented the data at Digestive Disease Week there was some incidence of neutralizing antibodies. Could you remind us of that? And also more importantly, tell us a little bit about what you're seeing in the ongoing trial if anything and your thoughts as to whether or not that might limit the sales potential for Nuvion?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

Sure. Just as a reminder, we presented at the DDW presentation that out of the 31 evaluated patients, and these were patients that had repeated anti-antibody tests out to day 90, that 6 patients were positive on a screening assay and 5 of those patients were confirmed to have a neutralizing antibody. These neutralizing antibodies were of relatively low titer in that they peak at day 30 and wane with additional time out to day 90. There was no impact in the outcome of this trial which administered a single dose. So the real question in terms of immunogenicity would really be a theoretical one around retreatment, whether or not this in fact would have any different — impact on retreatment. Having just retreated a handful of patients, it's too early for us to make any comments. We will update you with regards to the immunogenicity that we're observing with the dose escalations in the ongoing study during the meeting in Prague. But at this time we really don't have a lot of additional data.

Charles Duncan - - ***JMP Securities*** - ***Analyst***

And then another follow-on question for Glen. Was it true that you said that you would start an asthma trial in the fourth quarter? And if so, does that depend on you actually completing the partnership discussions?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

I'll take that. We've continued, even as we've had some discussions with potential partners, to commit to planning and getting trials in place to continue the asthma development program so that independent of a partnership we would intend to take this into the clinic with the next trial hopefully beginning in late fourth quarter. Obviously if there is a partnership that could have some influence on the design or the timing of the trials, but we'd certainly update you at the time that became apparent.

Charles Duncan - - ***JMP Securities*** - ***Analyst***

Okay, thank you, Steve.

Operator

Phil Nadeau, SG Cowen.

Phil Nadeau - ***SG Cowen*** - ***Analyst***

My first one is for you, Glen; it's just a housekeeping item on the new guidance. There's a line in the press release that says — that you're expecting an approximate 30 percent annual increase in royalty revenue. Is that still the case? My recollection is that was your previous guidance and if you're reiterating that it would seem like the majority of the increase in guidance today is coming from the license line?

Glen Sato - ***Protein Design Labs*** - ***CFO***

I think what we had said was that overall for revenue was 17 to 22 percent and that's because the other revenue or license line was actually falling. We continue to expect that to fall. We do, however, expect that royalties will continue to grow in excess of 30 percent obviously compensating for that and bringing us up to the 32 to 37 percent level increase compared to 2003 overall.

Phil Nadeau - ***SG Cowen*** - ***Analyst***

But you do continue to expect the licenses to fall?

Glen Sato - ***Protein Design Labs*** - ***CFO***

Yes, because that's new deal dependent. We did a lot of new deals last year in excess of $13 million and it's pretty tough to say we would exceed that.

Phil Nadeau - ***SG Cowen*** - ***Analyst***

Second one, Glen, is also for you. Could you give us some detail on the non-cash charges during the quarter?

Glen Sato - ***Protein Design Labs*** - ***CFO***

Sure. I guess the bulk of them, if you take a look at it, about $1.4 million related to stock based compensation expense and that relates really principally to a change in status from some individuals who went from employees to consultants as well as there's some termed employees. There's probably about $350,000, $360,000 I guess would be accurate of ongoing stock based compensation expense that's really a result of the original Eos acquisition a year ago. So I think really it relates to what I'd say the turnover in status of certain employees. I think it's kind of a quarterly event, although the number obviously will not decrease substantially on a going forward basis.

Phil Nadeau - ***SG Cowen*** - ***Analyst***

Okay. And my last question is in regards to the market potential for Nuvion. During the prepared remarks there was a comment made saying that the retreatment for the discontinuation or pausing of the retreatment trial doesn't affect the commercial opportunity for Nuvion. How do you see the commercial opportunity for Nuvion working out? What do you think its opportunity is if it's a single dose treatment and what would its opportunity be if you could give multiple doses?

Mark McDade - ***Protein Design Labs*** - ***CEO***

Phil, this is Mark. Let me try to address that. I think first in Steve's remarks on the — earlier he spoke to the fact that we don't believe the — any of the events related in the tested DLT's for Nuvion really affect our competitive position for an induction of remission label for Nuvion. So I think that's what he stated. Where we feel the product is positioned currently is in the most severe end of the spectrum of ulcerative colitis where those patients who have failed a course of intravenous steroid therapy go on to have their colon removed.

The data that we've generated suggests that that patient population is somewhere north of 20,000, somewhere between 20,000 and 30,000 is what the figures estimate and some small portion of those don't undergo a course of therapy; they just go straight to surgical removal. So it's a little hard to get an exact number. But the severe population, those who either undergo surgery or undergo first medical treatment and then might move to surgery at a later date is actually larger and that's approximately 42,000. So somewhere between 20,000 and 42,000 patients is perhaps a good way to look at the potential in the most severe end of this disease for the use of Nuvion.

At no time I think at any point where we first unveiled our estimates, which are a composite of figures from several sources, have we stated that those include an anticipation for retreatment. So we're really speaking to the true incidence as measured by surgical procedures and I think that's a pretty strict and conservative way to look at the market potential for this drug. So hopefully that answers your question, Phil.

Phil Nadeau - ***SG Cowen*** - ***Analyst***

Maybe just a quick follow-up. So what type of incremental opportunity would there be for a drug with retreatment as an option?

Mark McDade - ***Protein Design Labs*** - ***CEO***

Again, I think it's early to say based on the lack of data. If you look at the overall market data there are several ways to try to answer that. The severe end of the disease that are not hospitalized but still considered severe by a variety of measures, including endoscopy for example, that patient population is over 100,000 patients just in the United States alone. And I failed to mention that the previous numbers I spoke to were U.S. only figures and we think Europe might offer the same size potential. So to answer your question, retreatment could either extend just for that most severe and smallest population the opportunity to remain in disease-free state for those patients. And as we learn more about the drug and perhaps Steve can comment, but in combination with possibly other therapies we might be able to broaden in, many years from now, the opportunity for the use of the drug both in retreatment but also in treatment in combination with other drugs. Steve, do you want to add to that?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

Sure. First, I just want it to be very clear for everyone that while we're pursuing induction as the initial label, and that's what we're having discussions with the agency about — certainly it's our longer-term plan to pursue retreatment as an option. And the early

findings on a handful of patients in this study I really do not think are meaningful with regards to making any predictions about the ability to retreat with this antibody. It's just much too early in the course. We're still working on dose even in the induction treatment phase. We've chosen to go after induction because there's no treatment options for these patients with a significant unmet need. We believe that that's the fastest time to market. We would then follow that on with additional studies to expand the indications of Nuvion — as we learn more about the optimal way to dose the antibody.

Phil Nadeau - ***SG Cowen*** - ***Analyst***

Great, thank you.

Operator

(OPERATOR INSTRUCTIONS) Elise Wang, Smith Barney.

Elise Wang - ***Smith Barney Citigroup*** - ***Analyst***

Just to go back on your guidance a little bit to just get clarity; if I recall you had previously given us some goal of what your targeted number of additional patent licenses or humanization collaborations may be. Can you remind us what that target was and what you've already accomplished so far and so — how that factors into the revenues?

Glen Sato - ***Protein Design Labs*** - ***CFO***

Surely. Our target was 1 to 2 this year. We've already done 1 which we announced earlier this year with Abbott. So there's still one more to go but I think the focus for partnership has been on daclizumab and finding a collaborator there has been a priority. That's not to say that we're not looking at humanization in other licenses. There's always active discussions there. But I think from a priority standpoint and what's going to have been the most significant impact on the organization and us financially is daclizumab is pretty much the only priority at one level.

Elise Wang - ***Smith Barney Citigroup*** - ***Analyst***

And what kinds of arrangements are you looking for on daclizumab, what type of optimal terms are you looking for in terms of either participation or funding?

Mark McDade - ***Protein Design Labs*** - ***CEO***

I think part of the reason that Steve described our willingness to go ahead and continue the development path of asthma is that we feel as though we have financially the wherewithal to continue development if that was necessary or we couldn't get terms that we didn't feel were commensurate with the kind of profit-sharing or economics we wanted on a downstream basis. Ideally we would participate significantly in the development as well as in the process of that product opportunity.

Elise Wang - ***Smith Barney Citigroup*** - ***Analyst***

With the intention of perhaps having some co-rights in the North American region?

Mark McDade - ***Protein Design Labs*** - ***CEO***

That's correct. That's consistent with our overall strategy of having some North American rights where possible.

Elise Wang - ***Smith Barney Citigroup*** - ***Analyst***

And on HuZAF, what type of a collaboration are you looking for on that front? Obviously there is a fair amount of activity going on in Crohn's disease. How do you see HuZAF kind of fitting into the spectrum of available and perhaps upcoming therapies and how would that play into your discussions?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

Well, for HuZAF what we've noted in the initial trials which was only up to 2 IV doses was that the antibody seemed to have a very attractive safety profile. It was extremely well tolerated and did give us a good signal of activity in Crohn's disease. Currently the time to market for HuZAF in Crohn's disease and the changing competitive landscape in Crohn's disease certainly are factors that we're considering in terms of a need for a partner. What we're currently doing

is we've amended our ongoing open label trial of HuZAF; this was a study that was initially designed just to test the safety of 4 doses of IV HuZAF. We're now going to amend that and give up to 9 doses to really show that this is an appropriate and well tolerated therapy to be given on a more prolonged basis. At the same time, while there may be competition in Crohn's I think it's important to point out that interferon gamma might be a mediator in other diseases as well, other autoimmune diseases. And if we had a regimen that we could use safely for a prolonged period that would give us the option with a partner to explore those other indications as well.

Elise Wang - ***Smith Barney Citigroup*** - ***Analyst***

Okay. And just last question. Can you — I don't recall and I may have missed this, if you could tell us the dose levels that you're testing with M200 and the number of patients you're targeting to enroll in this study and what type of tumor types you're looking at?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

This is across a range of solid tumors, essentially it's patients with advanced solid tumors for whom there is no approved therapy. And when we look at the histologies enrolled it's really across the usual suspects of solid tumors. We are now going to trade up to 15 milligrams per kilogram. We've treated safely at 10 milligrams per kilogram. We want to get a wider safety range, so we're going to go up one more dose level to 15 milligrams per kilogram. And this study ultimately will have probably around 20 patients or so.

Elise Wang - ***Smith Barney Citigroup*** - ***Analyst***

Okay, thank you very much.

Operator

Gabe Hoffman, Asset (ph) Capital Management.

Gabe Hoffman - ***Asset Capital Management*** - ***Analyst***

Congratulations on the strong financial performance and thank you for taking the question. Just to clarify, in the retreatment trial once you hear back from the DSMB in about 2 weeks, assuming that things are "okay" then would the Company not be issuing any sort of press release? In other words, if the retreatment phase were to begin to retreat additional patients — would the Company have any kind of announcement?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

We had not intended to do that because we hadn't felt that it was sufficiently important given the way the study is designed. This is a typical course for early — in retreatment and we expect that following the appropriate safety review that we'll be retreating.

Gabe Hoffman - ***Asset Capital Management*** - ***Analyst***

And if the Company were not to be retreating at that time, would then there be some kind of announcement?

Mark McDade - ***Protein Design Labs*** - ***CEO***

If it were an affective Phase II portion which is the retreatment portion of the protocol then obviously that's something that would impact the timelines that we've discussed and potentially our registrational plan.

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

So without real changes in the study I think the next time that we would plan on making comments about the complete update of the current status would be during the presentation at the meeting in Prague.

Gabe Hoffman - ***Asset Capital Management*** - ***Analyst***

Are there any conceivable sort of feedback from the DSMB that would require the retreatment to be — to not continue yet that would somehow not affect the Phase II plans?

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

Currently we don't believe that a DSMB discussion at this point would really be relevant to either the ongoing Phase I or the Phase II component of the trial. It's simply we're treating those patients, establishing the safety in the Phase I and choose an optimal dose. So it probably should have no impact on the Phase II portion of the current trial. That's why we don't think that it's going to have an impact on the timeline.

Gabe Hoffman - ***Asset Capital Management*** - ***Analyst***

Okay, great. And just as a follow-up. On the 10b5-1 plans, would you be able to give a sense of which officers have gone into those and if you could give us any sense of roughly, just broad figures, quarter half, three-quarters of their holdings are to be sold over roughly what periods of time are we talking, a year, 2 years, 4 years?

Mark McDade - ***Protein Design Labs*** - ***CEO***

There will be more detail in the 10-Q in general for the significant holders over all of the executive officers but one have entered into the plan. There are limits which would represent I'd say a small portion of their overall holdings somewhere in the range of maybe up to 20 percent of their total holdings over a

number of years. So obviously it's case specific here.

Gabe Hoffman - ***Asset Capital Management*** - ***Analyst***

Great, thank you. That's very helpful.

Operator

(OPERATOR INSTRUCTIONS) Hui Shao, Mehta Partners.

Hui Shao - ***Mehta Partners*** - ***Analyst***

Congratulations on the strong financial numbers. I guess most of the questions have been answered. I just have a last question related to the housekeeping issue. Glen, can you provide the latest number on the long-term debt on your balance sheet?

Glen Sato - ***Protein Design Labs*** - ***CFO***

It should be about $270 million.

Hui Shao - ***Mehta Partners*** - ***Analyst***

Okay. What's the maturity date?

Glen Sato - ***Protein Design Labs*** - ***CFO***

Which is the convertible. $250 million of that's the convertible and then there are additional — long-term debt that related to the acquisition of Eos. Hold on for one second, let me go ahead and get that information for you. It's about $260 million.

Hui Shao - ***Mehta Partners*** - ***Analyst***

Okay, thank you.

Operator

Greg Wade, Pacific Growth Equities.

Greg Wade - ***Pacific Growth Equities*** - ***Analyst***

Thanks for taking my question. Steve, a couple questions on Nuvion. Can you update us on your plans for Nuvion in Crohn's disease and any preclinical findings with respect to where the T-cells are going in people, whether they're being depleted or just coming out of the circulation? And then lastly, maybe give us some insight into the tolerability with the new pre-treatment regimens that you're using in the ongoing studies? Thanks.

Dr. Steven Benner - ***Protein Design Labs*** - ***Chief Medical Officer***

Sure, Greg. With regards to the Crohn's disease we're currently planning 2 pilot trials, 1 in fistulizing Crohn's disease and 1 in severe active disease just as an initial exploration. We've been talking about the trial designs; these would be relatively small studies which could get up and running as early as the end of the fourth quarter of this year. With regards to the T-cells, we're actively looking at the additional tests of the mechanism of action. As we have talked about at DDW, there's no question that active apoptosis is clearly one of the significant mechanisms of action if not the most significant mechanism of action for Nuvion. We see a prompt decline in circulating T-cell counts and signs of apoptosis.

The redistributed question is one that's still open at this time. We're trying to look for ways in which we might image to get a better handle on that, but at the present time we really don't have a lot of new information to update you with. Finally, with regard to tolerability, we believe that with a combination of the lower doses that we're using in the current trial, as well as the premedication regimen which included hydration, Tylenol, Benedryl and an anti hemetic, that therapy has been better tolerated in the ongoing Phase I/II study. We still see a majority of patients having some symptoms of cytokine release — much more common on day 1 than day 2. But the intensity of those symptoms have clearly been less in the ongoing study than they were in the initial trial.

Greg Wade - ***Pacific Growth Equities*** - ***Analyst***

Great. Thanks for taking my questions.

Operator

Ron Ellis, Leerink Swann

Ron Ellis – ***Leerink Swann*** - ***Analyst***

Glen, a question for you and thanks for taking the call. Just for the guidance on profitability, does that change at all with increasing the top line guidance? And then just any sense of when the aggregate DNA sales may trigger the (indiscernible) 2 reduction if there's any change in guidance for that?

Glen Sato - ***Protein Design Labs*** - ***CFO***

On the last question we haven't given guidance instance, Ron, so I can't give you an update on that one. And we still, by virtue of our relationship with Genentech, don't plan to provide guidance on when those reductions would actually kick in. Obviously sooner would be preferable from our standpoint because obviously sales would then be exceeding our expectations. With respect to cash flow breakeven or better, I hesitate to use the term "profitability" again in the face of stock option expensing which we fully expect to be the case in 2005 or 2006. So we talk about it from the standpoint of cash flow breakeven or better, that would tie to the first launch — first full year of launch of our products so we haven't changed those expectations at all which would be at the earliest 2007.

Ron Ellis – *Leerink Swann - Analyst*

All right, thank you.

Operator

Mr. Goff, there are no more questions at this time. I will now turn the call back to you. Please continue with your presentation or with your closing remarks.

Jim Goff - *Protein Design Labs – Sr. Director, Corp. Communications*

Thank you, operator. Just before we close I'd like to remind everyone that in addition to the data presentations at UEGW in Prague and the EORTC-NCI-AACR meeting in Geneva in late September, PDL will also present at the UBS investor conference in September. And as we mentioned in the press release we currently plan to conduct an R&D day in New York City shortly following the European medical conferences. And that PDL event is tentatively planned for the second week of October. We hope you'll look forward for further information on that event. So with that I thank you, everyone, and have a good afternoon.

Operator

Ladies and gentlemen, that does conclude the conference call for today. We thank you for your participation and ask that you please disconnect your lines.