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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## 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):

March 14, 2005

## PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation)

000-19756

(Commission File No.)

94-3023969

(I.R.S. Employer Identification  
No.)

34801 Campus Drive

Fremont, California 94555

(Address of principal executive offices)

Registrant's telephone number, including area code:

(510) 574-1400

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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#### Item 2.02. Results of Operations and Financial Condition

On March 14, 2005, the Company issued a press release (the "Press Release") announcing the Company's financial results for the fiscal quarter ended December 31, 2004 (the "Results") and held a conference call regarding those Results (the "Conference Call"). The Press Release and a 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.

#### Use of Non-GAAP Financial Information

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

#### Item 9.01 Financial Statements and Exhibits.

##### (c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 14, 2004, regarding the fourth quarter 2004 financial results of Protein Design Labs, Inc.
99.2	Transcript of earnings call, held on March 14, 2004, regarding the fourth quarter 2004 financial results of Protein Design Labs, Inc.

**SIGNATURES**

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

Date: March 16, 2005

**PROTEIN DESIGN LABS, INC.**

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



For Immediate Release

Contact:

James R. Goff  
Senior Director,  
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**PROTEIN DESIGN LABS ANNOUNCES ABOVE CONSENSUS FULL-YEAR  
AND FOURTH QUARTER 2004 FINANCIAL RESULTS  
AND PROVIDES 2005 UPDATE AND GUIDANCE**

**Company projects year of rapid transformation following anticipated late-March  
closing of acquisitions of ESP Pharma and Retavase®**

Fremont, Calif., March 14, 2005 – Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported a net loss of \$53.2 million, or \$0.56 per basic and diluted share, for the year ended December 31, 2004, compared with a net loss of \$129.8 million, or \$1.40 per basic and diluted share, for the year ended December 31, 2003. Excluding certain non-cash charges described in more detail below, the non-GAAP net loss for 2004 would have been \$49.4 million, or \$0.52 per basic and diluted share, compared with a non-GAAP net loss of \$35.9 million, or \$0.39 per basic and diluted share in 2003.

Total revenues in 2004 were \$96.0 million, an increase of 44% over total revenues of \$66.7 million in 2003. The increase included a 59% increase in royalties, which totaled \$83.8 million in 2004, compared with royalty revenues of \$52.7 million in 2003. License and other revenues of \$12.2 million in 2004 decreased from \$14.0 million in the prior year.

As of December 31, 2004, PDL had cash, cash equivalents, marketable securities and restricted investments totaling approximately \$397.1 million, compared with \$505.0 million at December 31, 2003. The December 31, 2004 balances reflected approximately \$95.7 million in capital expenditures made during 2004, primarily related to planned ongoing construction and validation of PDL's manufacturing plant at Brooklyn Park, Minn.

Total costs and expenses were \$154.4 million in 2004, compared with \$196.3 million in 2003. Excluding certain non-cash charges, which consist of acquired in-process research and development charges and the amortization of intangible assets associated with the Eos acquisition and the re-acquisition of rights to manufacture and market Zenapax® (daclizumab) in 2003, restructuring charges related to the closure of PDL's New Jersey facility in the second quarter of 2004, as well as stock-based compensation charges, non-GAAP total costs and expenses in 2004 would have been \$150.5 million compared to non-GAAP expenses of \$109.1 million for 2003.

Research and development expenses increased 48% to \$122.6 million in 2004, compared with \$82.7 million in 2003. The increase in research and development expenses reflected additional headcount and associated costs required to pursue research and clinical development programs, contract manufacturing and direct scale-up

**Protein Design Labs, Inc.**

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and manufacturing expense, increased facility and equipment-related costs, and in-licensing of technology. General and administrative expenses increased to \$31.8 million in 2004 from \$27.6 million in 2003.

Total revenues during the fourth quarter of 2004 were \$22.8 million, compared with \$13.6 million in the fourth quarter of 2003. Royalties in the fourth quarter of 2004 were \$19.9 million, or 124% higher than the \$8.9 million of royalties reported in the 2003 fourth quarter. License and other revenues were \$2.9 million and \$4.7 million in the 2004 and 2003 fourth quarters, respectively. Research and development expenses were \$30.2 million in the fourth quarter of 2004, compared with \$24.4 million in the comparable three months of 2003. General and administrative expenses were \$8.6 million and \$8.1 million in the fourth quarters of 2004 and 2003, respectively. PDL reported a net loss of \$14.6 million, or \$0.15 per basic and diluted share, for the fourth quarter of 2004, compared with a net loss of \$72.9 million, or \$0.78 per basic and diluted share, in the same period in 2003, which included an acquired in-process research and development expense of \$48.2 million related to the re-acquisition from Roche of rights to develop and market Zenapax in indications other than transplantation as well as an option to re-acquire rights in transplantation. Excluding certain non-cash charges, the non-GAAP net loss in the fourth quarter of 2004 would have been \$13.7 million, or \$0.14 per basic and diluted share, compared with a non-GAAP net loss of \$17.6 million, or \$0.19 per basic and diluted share in the comparable period of 2003.

Reconciliations of our GAAP results to our non-GAAP results are included in the financial results accompanying this release.

**Recent Corporate Developments**

On January 25, 2005, PDL and ESP Pharma, a privately held, sales and marketing-focused pharmaceutical company, announced a definitive agreement under which PDL would acquire ESP Pharma and its pipeline of marketed products and clinical candidates for \$300 million in cash and approximately \$175 million in PDL common stock, or an aggregate value of approximately \$475 million, plus the assumption of net debt anticipated to be

approximately \$14 million at the time of closing. In February 2005, ESP Pharma agreed to acquire from Centocor, Inc., a biopharmaceutical operating company of Johnson & Johnson, rights to manufacture, develop, market and distribute Retavase<sup>®</sup> (reteplase) in the United States and Canada for \$110 million and milestone payments of up to \$45 million if additional conditions relating to ongoing clinical trials and manufacturing arrangements are satisfied. As a result of ESP Pharma's purchase of Retavase, PDL agreed to increase the purchase price paid to ESP Pharma's shareholders by \$25 million in cash payable at closing of the ESP Pharma acquisition, and agreed to assume the purchase price obligations to Centocor under the agreement.

"By adding marketed products and sales and distribution capabilities to our antibody development and humanization technology platform, the ESP Pharma acquisition is intended to establish PDL as a fully integrated, commercial biopharmaceutical company with a diverse revenue base and a broad, proprietary pipeline," said Mark McDade, Chief Executive Officer, PDL.

"The Retavase acquisition enhances the utilization of the sales force and provides us with another point of entry into the emergency room. In addition, the acquisition of this commercial infrastructure should put us in an excellent position for the potential future

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launches of Nuvion and other hospital products. Moreover, these combined acquisitions should enable us to become cash-flow positive beginning in the second half of 2006," Mr. McDade added.

PDL currently anticipates closing its pending acquisition of ESP Pharma late in the first quarter or early in the second quarter of 2005, subject to regulatory approvals and the satisfaction of closing conditions under the agreement.

### 2005 Forward-looking Guidance

*The following statements are based on expectations as of March 14, 2005. These statements are forward-looking, and actual results may differ materially. This guidance assumes closing of the ESP Pharma and Retavase acquisitions on or about March 31, 2005. Except for those assumptions and as expressly set forth below, these statements do not include the potential impact of new collaborations, material licensing arrangements or other strategic transactions.*

For 2005 PDL anticipates that, on a non-GAAP basis, our total revenues will be in the range of approximately \$250 to \$260 million. Royalty revenues are expected to be in the range of approximately \$112 to \$115 million, and license and other revenues are anticipated to be in the range of approximately \$20 to \$25 million. Royalty revenue estimates do not include further royalties based on sales of Tysabri<sup>®</sup> antibody product from Biogen Idec and Elan, which is licensed under PDL's humanization patents but was withdrawn from the market on February 28, 2005. PDL currently believes that royalty revenues for each year from 2006 through 2008 should grow approximately 25% per year.

Product revenues for Cardene IV, Retavase and IV Busulfex are expected to total approximately \$93 to \$95 million for the anticipated nine-month period of sales following the close of the acquisition of ESP Pharma on or about March 31, 2005. Additionally, PDL anticipates compound annual growth rates of approximately 25% for net product sales of these three marketed products for each year from 2006 through 2008. For these same products, PDL currently anticipates product operating margins of at least 80% over the 2005 through 2008 period.

During 2005 we anticipate research and development expenses in the range of \$184 to \$186 million of which we expect to spend approximately \$100 million to advance our clinical development programs for Nuvion, daclizumab and M200. We further anticipate sales and marketing expenses in the range of \$42 to \$44 million resulting primarily from the ESP Pharma acquisition. We anticipate general and administrative expenses for the full year 2005 in the range of \$31 to \$33 million.

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

Overall, for the full year 2005 we anticipate a GAAP net loss in the range of approximately \$1.43 to \$1.64 per basic and diluted share, and a non-GAAP net loss in the range of approximately \$0.18 to \$0.34 per basic and diluted share.

At year-end 2005, PDL estimates that its cash balances will be approximately \$200 million. This estimate takes into account anticipated capital expenditures of \$38 to \$42 million, approximately half of which represents final validation and completion of our

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new Brooklyn Park, Minn. manufacturing facility; cash payments during 2005 of \$325 million and \$110 million for the acquisitions of ESP Pharma and Retavase, respectively; the receipt of approximately \$240 million from the recent sale of convertible notes, net of fees and expenses; and the assumption of up to \$14 million in ESP-related debt. By year-end 2005, we estimate that our headcount will be in the range of 900 to 950, split approximately 70% in research and development, 15% in sales and marketing and 15% in general and administrative functions.

The 2005 non-GAAP operating expenses exclude the following: (a) stock compensation expenses of approximately \$10 to \$15 million (noting that this is a highly variable expense depending upon the valuation model selected and related assumptions for stock price volatility); (b) acquired in-process research and development expenses related to the purchase of ESP Pharma of approximately \$88 million; and (c) amortization of intangibles related to the acquisitions of Eos, ESP Pharma and to our recent convertible offering of approximately \$31 million. We note that the stock compensation expense is a preliminary estimate based on the new standard issued by the Financial Accounting Standards Board, FAS 123R, to be adopted by us in the second half of 2005. The actual expense may be materially different depending on the assumptions and methodologies used in implementing the new standard.

### Clinical Development Update

Dr. Steven Benner, Senior Vice President and Chief Medical Officer, PDL, said, "PDL is committed to the development of new antibody-based treatments. We have continued to make progress on our clinical programs and look forward to exciting new antibody programs leading to future INDs coming from our research efforts. Now, with the anticipated acquisition of ESP Pharma, we expect to add additional clinical programs that we hope will expand our product portfolio over the next few years."

**Nuvion (visilizumab, anti-CD3).** Nuvion remains PDL's highest development priority. PDL expects to meet with the FDA in late March. At this end-of-Phase I meeting, PDL will discuss its plans to move Nuvion into a Phase III program. PDL hopes to move into registrational trials with Nuvion in intravenous corticosteroid-refractory ulcerative colitis late this year. If the discussions with the FDA are positive, PDL intends to use the FDA's Special Protocol Assessment process to continue to develop the protocol and plan the analysis of the Phase III program.

PDL expects to publicly update the status of its Nuvion program and the outcome of the discussion with the FDA by early April. Additional data from the Phase I / II study of Nuvion is expected to be presented during the Digestive Disease Week meeting to be held in Chicago from May 14-19.

**Daclizumab (Zenapax, anti-IL-2 receptor).** PDL is on schedule to begin in this quarter a single-dose Phase I study of PDL-manufactured daclizumab administered subcutaneously for asthma. This trial will be followed by a multiple-dose study in healthy volunteers expected to be initiated this summer. A Phase II dose range-finding study of subcutaneously administered, PDL-manufactured daclizumab in asthma patients remains on schedule for the first quarter of 2006. PDL also continues to evaluate the opportunity to develop daclizumab further in the setting of solid organ transplantation.

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

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

In addition, PDL is planning a pilot trial of M200 administered intravenously in patients with age-related macular degeneration (AMD). M200 administered intravenously has shown activity in animal models and this approach reflects PDL's belief that the treatment of this disease will evolve to systemic therapies. Consequently, given the attractiveness of this approach relative to intra-vitreal injections, we intend to proceed with development of M200 in place of F200 in this indication. F200 is a fragment of the M200 antibody and was a pre-IND candidate for the intra-vitreal treatment of AMD. We are planning a Phase II trial of M200 administered intravenously in patients with AMD, expected to begin during the second half of 2005.

## ESP Pharma Products and Pipeline

ESP Pharma's two leading marketed products are Cardene IV and IV Busulfex, and it is under contract to acquire an additional marketed product, Retavase, from Centocor. The 75 sales professionals at ESP Pharma currently detail to hospital-based physicians the following products:

**Cardene IV<sup>®</sup> (nicardipine hydrochloride).** Cardene IV is indicated for the short-term treatment of hypertension when oral therapy is not feasible or desirable. Cardene IV is used in the hospital as an option for control of hypertension. Currently, it is used most often by neurologists, neurosurgeons, anesthesiologists, cardiologists and cardiothoracic surgeons. Increasingly, it also is used in emergency departments. We believe that given the known safety profile and efficacy of Cardene IV, the use of this agent will continue to increase as new prescribers gain experience with the agent. We will be evaluating additional opportunities to further develop Cardene IV.

**IV Busulfex<sup>®</sup> (busulfan injection).** IV Busulfex is an intravenous formulation of busulfan and is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. When used in this regimen, IV Busulfex is administered four times per day and replaces oral busulfan, for which a patient must take over 100 pills per day. Oral busulfan is associated with nausea and vomiting that may lead to lower drug levels than was intended. We believe that additional opportunities for the development of IV Busulfex exist. We may explore other potential uses of the drug, such as a once per day regimen and expanding the use of the drug into other conditioning regimens for the

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treatment of other malignancies. We expect that the major use of IV Busulfex will be in conditioning regimens associated with bone marrow transplantations.

**Retavase<sup>®</sup> (reteplase).** Retavase is indicated for use in the management of acute myocardial infarction (AMI) in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure and the reduction of mortality associated with AMI. Retavase is used predominantly by cardiologists, cardiothoracic surgeons and emergency room physicians. PDL believes that the two bolus, fixed-dosing regimen of Retavase is an advantage in the acute setting of myocardial infarction. We believe that Retavase will be an excellent fit with Cardene IV, as there is significant overlap in the hospitals and physicians that could use both products. With respect to further development opportunities for Retavase, an ongoing clinical trial being conducted by Centocor and Eli Lilly and Company, called the FINESSE trial, is exploring the use of Retavase in combination with Reopro<sup>®</sup> (abciximab) in the setting of facilitated percutaneous coronary intervention (PCI).

ESP Pharma has marketing rights for three compounds in development, as well as Phase III development and marketing rights for a fourth compound. PDL has prioritized the pipeline to focus immediately on two of these opportunities: terlipressin, a potential treatment for hepato-renal syndrome (HRS); and ESP-305, a potential treatment for congestive heart failure.

**Terlipressin.** Terlipressin is a synthetic 12 amino acid peptide derived from the naturally occurring lysine-vasopressin. Terlipressin causes constrictive activity in vascular and extra-vascular smooth muscle. As a consequence, it reduces blood flow in the splanchnic area and thereby lowers portal blood pressure. Terlipressin is approved in many European and Asian countries for the treatment of esophageal variceal hemorrhage. These varices develop as a complication of portal hypertension in patients with liver cirrhosis.

Results from early clinical trials suggest that terlipressin may have activity in patients with hepato-renal syndrome (HRS). Patients with end-stage liver disease may develop progressive deterioration of renal function, without a primary abnormality of the kidney. Patients who have a rapid decline of renal function, characterized as HRS type I, have a median survival of less than two weeks. The treatment of choice for these patients is liver transplantation, but this option is not always available to all patients.

ESP Pharma acquired exclusive marketing rights for terlipressin in the United States and Canada from a private U.S. company, Orphan Therapeutics, which is developing the compound in HRS. Orphan Therapeutics holds the IND and is conducting a Phase III trial in patients with type I HRS in the United States and Europe.

Orphan Therapeutics has obtained Orphan Drug Status for this program. We estimate that there are 4,000 to 6,000 patients in the United States each year that could be candidates for this therapy. There are no approved medical treatments for type I HRS.

**ESP-305 (ularitide).** ESP-305 is an agent for the potential treatment of congestive heart failure. This compound is a natriuretic peptide, urodilatin (INN: ularitide). Ularitide is a recombinant form of this naturally occurring peptide, originally isolated from human urine. Ularitide is formed from the cleavage of the same prohormone that produces atrial natriuretic peptide. Ularitide enhanced natriuresis and diuresis and

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decreased central venous pressure in a previous small study of patients with CHF. The peptide was first isolated by scientists affiliated with the University of Hanover, Institute of Peptide Research and has been developed by a German company, CardioPep Pharma GmbH.

Recently, CardioPep has been conducting clinical studies of ularitide in hospitalized patients with decompensated congestive heart failure. The first of their two studies, the SIRIUS I trial, was a double-blind, placebo-controlled, ascending dose study in patients with decompensated chronic heart failure. This trial enrolled 24 patients. The study was primarily intended to assess safety, but evidence of hemodynamic activity was observed at two higher dose levels when assessed at six hours. There was no apparent difference in adverse events across the four treatment groups. The results of this study, SIRIUS I, are now in press in the American Heart Journal. Currently, CardioPep is conducting SIRIUS II, a larger, double-blind, placebo-controlled Phase II study of ularitide. A total of 221 patients have been enrolled. Results of this trial should become available in the second quarter of this year.

ESP Pharma acquired from CardioPep exclusive rights to conduct all subsequent Phase III development and exclusive marketing rights for ularitide for all indications in the United States, Canada, the European Union and Switzerland. To date, all clinical development of ularitide has taken place in Europe. PDL anticipates filing a U.S. IND for ESP-305 this year. In the United States alone, there are approximately one million hospitalizations per year for decompensated congestive heart failure.

Dr. Benner added, "We are pleased that the ESP Pharma projects will enter our pipeline at the end of Phase II or later and that the combined pipeline will maintain a focus on hospital products, while expanding PDL into cardiology. We are very excited about not only becoming a fully integrated company, but about the broader potential of our commercial portfolio with new products that are currently in development."

#### **Webcast Information**

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its financial results for the fourth quarter and year ended December 31, 2004, the status of its clinical development programs, the status of its pending acquisition of ESP Pharma, and its forward-looking information and guidance with respect to future results. Financial and statistical information to be discussed in the call will be available on the PDL website immediately prior to the commencement of the call. A link to the conference call webcast will be available through the PDL website: [www.pdl.com](http://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](http://www.pdl.com) starting approximately one hour after completion of the webcast. A replay of the conference call will also be available by telephone from approximately 7 p.m. Eastern time on March 14 through 7 p.m. Eastern time on March 20, 2005. To access the replay, dial 800-633-8284 from inside the United States and 402-977-9140 from outside the United States and enter conference ID number 21233659.

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The foregoing contains forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those, express or implied,

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

Further, there can be no assurance that results from completed and ongoing clinical studies, described above, will be successful or that ongoing or planned clinical studies will be completed or initiated on the anticipated schedules. In particular, there can be no assurance that our scheduled meeting with the FDA regarding *Nuvion* later in this quarter will result in our ability to initiate potentially pivotal studies prior to year end, if ever. Other factors that may cause our actual results to differ materially from those, express or implied, in the forward-looking statements in this press release are discussed in our filings with the Securities and Exchange Commission. PDL expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any

forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

## About PDL

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](http://www.pdl.com) or by contacting James R. Goff, Senior Director, PDL Corporate Communications, (510) 574-1421 or [jgoff@pdl.com](mailto:jgoff@pdl.com).

Protein Design Labs, the PDL logo and Nuvion are registered U.S. trademarks of Protein Design Labs, Inc. Zenapax is a registered trademark of Roche. Synagis is a registered U.S. trademark of MedImmune, Inc. Avastin is a trademark of Genentech, Inc. Cardene IV and IV Busulfex are registered trademarks of ESP Pharma, Inc. Retavase is a registered trademark of Centocor. Tysabri is a trademark of Elan.

Financial tables attached.

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

(In thousands, except per share data)	Three months ended December 31,		Years ended December 31,	
	2004	2003	2004	2003
<b>Revenues:</b>				
Royalties	\$ 19,935	\$ 8,896	\$ 83,807	\$ 52,704
License and other	2,894	4,717	12,217	13,982
Total revenues	22,829	13,613	96,024	66,686
<b>Costs and expenses:</b>				
Research and development	30,199	24,409	122,563	82,732
General and administrative	8,624	8,148	31,806	27,613
Acquired in-process research and development	—	48,159	—	85,993
Total costs and expenses	38,823	80,716	154,369	196,338
Operating loss	(15,994)	(67,103)	(58,345)	(129,652)
Interest and other income, net	2,523	(3,320)	10,212	9,831
Interest expense	(1,099)	(2,424)	(5,028)	(9,770)
Impairment loss on investment	—	—	—	(150)
Loss before income taxes	(14,570)	(72,847)	(53,161)	(129,741)
Provision for income taxes	12	12	80	73
<b>Net loss</b>	<b>\$ (14,582)</b>	<b>\$ (72,859)</b>	<b>\$ (53,241)</b>	<b>\$ (129,814)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.15)</b>	<b>\$ (0.78)</b>	<b>\$ (0.56)</b>	<b>\$ (1.40)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>95,613</b>	<b>93,764</b>	<b>94,982</b>	<b>92,478</b>

### CONSOLIDATED BALANCE SHEET DATA (Unaudited)

(In thousands)	December 31,	December 31,
	2004	2003*
	(unaudited)	
Cash, cash equivalents, marketable securities, and restricted investments	\$ 397,080	\$ 504,993
Total assets	713,732	742,030
Total stockholders' equity	412,510	448,331

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

We use non-GAAP amounts that exclude charges related to acquired in-process research and development and certain other non-cash charges, including amortization of intangible assets, and stock-based compensation, as well as other non-recurring charges, such as costs incurred in connection with the extinguishment of our debt and restructuring charges. Management believes that these non-GAAP measures enhance an investor's overall understanding of our financial performance and future prospects by reconciling more closely to the actual cash expenses of the company in its operations, as well as excluding expenses that, in management's view, are unrelated to our core operations, the inclusion of which may make it more difficult for investors and financial analysts reporting on the company to compare our results from period to period. Our management uses these non-GAAP financial measures along with the most directly comparable GAAP financial measures in evaluating the company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)	Three months ended December 31,					
	2004			2003		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
<b>Revenues:</b>						
Royalties	\$ 19,935		\$ 19,935	\$ 8,896		\$ 8,896
License and other	2,894		2,894	4,717		4,717
<b>Total revenues</b>	<b>22,829</b>		<b>22,829</b>	<b>13,613</b>		<b>13,613</b>
<b>Costs and expenses:</b>						
Research and development	30,199	\$ (598)(1)	29,601	24,409	\$ (595)(1)	23,814
General and administrative	8,624	(303)(1)	8,321	8,148	(14)(1)	8,134
Acquired in-process research and development	—	—	—	48,159	(48,159)(2)	—
<b>Total costs and expenses</b>	<b>38,823</b>	<b>(901)</b>	<b>37,922</b>	<b>80,716</b>	<b>(48,768)</b>	<b>31,948</b>
Operating loss	(15,994)	901	(15,093)	(67,103)	48,768	(18,335)
Interest and other income, net	2,523	—	2,523	(3,320)	6,538(3)	3,218
Interest expense	(1,099)	—	(1,099)	(2,424)	—	(2,424)
Impairment loss on investment	—	—	—	—	—	—
Loss before income taxes	(14,570)	901	(13,669)	(72,847)	55,306	(17,541)
Provision for income taxes	12	—	12	12	—	12
<b>Net loss</b>	<b>\$ (14,582)</b>	<b>\$ 901</b>	<b>\$ (13,681)</b>	<b>\$ (72,859)</b>	<b>\$ 55,306</b>	<b>\$ (17,553)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.15)</b>		<b>\$ (0.14)</b>	<b>\$ (0.78)</b>		<b>\$ (0.19)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>95,613</b>		<b>95,613</b>	<b>93,764</b>		<b>93,764</b>

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

(2) To exclude the non-cash charges of acquired in-process research and development, 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.

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

We use non-GAAP amounts that exclude charges related to acquired in-process research and development and certain other non-cash charges, including amortization of intangible assets, and stock-based compensation, as well as other non-recurring charges, such as costs incurred in connection with the extinguishment of our debt, impairment losses and restructuring charges. Management believes that these non-GAAP measures enhance an investor's overall understanding of our financial performance and future prospects by reconciling more closely to the actual cash expenses of the company in its operations, as well as excluding expenses that, in management's view, are unrelated to our core operations, the inclusion of which may make it more difficult for investors and financial analysts reporting on the company to compare our results from period to period. Our management uses these non-GAAP financial measures along with the most directly comparable GAAP financial measures in evaluating the company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)	Years ended December 31,					
	2004			2003		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
<b>Revenues:</b>						
Royalties	\$ 83,807		\$ 83,807	\$ 52,704		\$ 52,704
License and other	12,217		12,217	13,982		13,982
<b>Total revenues</b>	<b>96,024</b>		<b>96,024</b>	<b>66,686</b>		<b>66,686</b>
<b>Costs and expenses:</b>						



Research and development	122,563	\$ (3,217)(1)	119,346	82,732	\$ (939)(1)	81,793
General and administrative	31,806	(655)(1)	31,151	27,613	(278)(1)	27,335
Acquired in-process research and development	—	—	—	85,993	(85,993)(2)	—
Total costs and expenses	154,369	(3,872)	150,497	196,338	(87,210)	109,128
Operating loss	(58,345)	3,872	(54,473)	(129,652)	87,210	(42,442)
Interest and other income, net	10,212	—	10,212	9,831	6,538(3)	16,369
Interest expense	(5,028)	—	(5,028)	(9,770)	—	(9,770)
Impairment loss on investment	—	—	—	(150)	150(4)	—
Loss before income taxes	(53,161)	3,872	(49,289)	(129,741)	93,898	(35,843)
Provision for income taxes	80	—	80	73	—	73
<b>Net loss</b>	<b>\$ (53,241)</b>	<b>\$ 3,872</b>	<b>\$ (49,369)</b>	<b>\$ (129,814)</b>	<b>\$ 93,898</b>	<b>\$ (35,916)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.56)</b>		<b>\$ (0.52)</b>	<b>\$ (1.40)</b>		<b>\$ (0.39)</b>
<b>Shares used in computation of basic and diluted net loss per share</b>	<b>94,982</b>		<b>94,982</b>	<b>92,478</b>		<b>92,478</b>

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

(2) To exclude the non-cash charges of acquired in-process research and development, 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.



## Conference Call Transcript

### PDLI - Q4 2004 Protein Design Labs Earnings Conference Call

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*Protein Design Labs - CEO & Director*

### Steven Benner, M.D.

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## PRESENTATION

### Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Protein Design Labs fourth quarter 2004 earnings conference call. During the presentation, all participants will be in a listen-only mode. Afterwards, we will conduct a question and answer session. At that time, if you have a question, please press the 1 followed by the 4 on your telephone. As a reminder, this conference is being recorded, Monday, March 14, 2005. I would now like to turn the conference over to Mr. Jim Goff, Senior Director of Corporate Communications. Please go ahead, sir.

**Jim Goff - Protein Design Labs - Senior Director - Corporate Communications**

Good afternoon, everyone, and thank you for joining us today. With me are Mark McDade, Chief Executive Officer; Glen Sato, our Chief Financial Officer and Dr. Steven Benner, our Chief Medical Officer. During today's call, we intend to briefly review PDL's full year and fourth quarter 2004 results, provide forward-looking financial guidance for 2005, and offer additional information relating to our recently announced M&A activity.

As we begin, I remind you that the information we'll cover today contains forward-looking statements regarding our financial performance, clinical milestones and other matters, and our actual results may differ materially from those expressed or implied in the forward-looking statements. Factors that may cause differences between current expectations and actual results are described in our filings with the Securities and Exchange Commission. Our intent today is to provide a view into where PDL is going, and our pending acquisitions are a significant part of that. As a reminder, these transactions are not closed, but we expect them to close in the near future. I will now turn the call over to Mark McDade, Chief Executive Officer.

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

Thank you, Jim. And to all of you joining, thank you for participating in today's important and intentionally extended call. I'll begin with a brief overview of our recent efforts and new direction, and turn it over to Steve Benner to describe our pipeline progress, together with the new ESP Pharma marketed product and developmental program opportunities. Glen Sato will then recap financial performance for 2004 and provide 2005 and longer range financial guidance; following which, I will provide some closing comments before opening the discussion to Q&A.

The last 14 months have been a busy and productive time for the PDL team. Notwithstanding the somewhat turbulent times in Biotech, I've never been more excited about our prospects. We recently announced agreements to acquire both ESP Pharma and the marketed drug Retavase, which taken together, after their expected close later this month, are truly transforming events for PDL. As you know, shortly after I joined this company in late 2002, we put in motion a five-year strategic plan that would evolve PDL into a commercial enterprise by 2007. Well, we're going to get there a lot sooner, as these transactions will bring us a portfolio of approved hospital-based drugs, along with the capacity to commercialize PDL's internally-developed products, and positive cash flow from operations on a quarterly basis, beginning in the second half of 2006.

Let me be very clear about our forward vision for the new PDL. We did not make these transactions to turn away from our mission of developing innovative therapies from our enabling technology platform. We are not becoming a specialty pharma company. Instead, we acquired one to harness its important commercialization capabilities that are currently missing at PDL to enable us to execute on our plan to become a fully integrated biotech company. The ESP Pharma acquisition provides PDL with immediate access to hospitals with a proven sales organization and several important marketed therapeutics. We anticipate that all key sales executives will be retained, and that we'll also retain the experienced, hospital focused sales team.

The Retavase acquisition enhances the utilization of the sales force and provides us with another point of entry into the ER. We intend to exploit the sales team's presence in nearly two-thirds of our targeted hospital universe for the future commercialization of PDL's antibody-based therapies. And we expect to expand the sales force over the course of 2005 to maximize and accelerate the opportunity for the marketed products that we'll discuss in just a few moments. The acquisition of this commercial infrastructure should put us in an excellent position for the potential future launch of Nuvion and other hospital-based products, while mitigating the financial risk of building such valuable expertise in advance of owning an existing approved therapeutic. The heart of an outstanding biotech is its pipeline. Ours is advancing and growing. We're within weeks of meeting with the FDA to seek to advance Nuvion to Phase III. We've moved M200 into the second of four planned Phase II studies in cancer; we're hard at work with Roche in progressing our new subcutaneous formulation of daclizumab ahead in Phase I studies geared toward 2006 Phase II studies. And we expect to treat the first patients in the upcoming daclizumab MS Phase II study within the next four to six weeks. I'm also excited about the future prospects for at least two of the acquired development stage compounds from ESP Pharma, which Steve will describe momentarily. If these plans progress over the ensuing three quarters, at year end 2005, PDL could potentially have rights to three Phase III programs in development, with Nuvion and two additional ESP licensed drugs, addressing unmet medical needs of significant numbers of patients.

We should end the year with more than enough cash to grow beyond positive cash flow, which should begin in the second half of 2006. And we'll own a newly integrated commercial infrastructure, focused on growing product and royalty revenue at least 25 percent per annum between now and the end of 2008. That's what's so exciting and at the heart of the new PDL — a proprietary and broad pipeline, growing and diversified revenues from products and royalties, and financial strength, all driven by a focused and talented team.

At this time, I will ask Dr. Steven Benner, our Chief Medical Officer, to present the status of PDL's clinical pipeline and our development priorities for 2005. Steve will also provide an overview of the products and pipeline to be acquired through the ESP Pharma and Retavase transactions. Steve?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

Thank you, Mark.

I want to reinforce the message that PDL is committed to the continued development and commercialization of new antibody-based treatments. The pending acquisition allows us to forward integrate in preparation for the potential approval and launch of our proprietary products. I would like to start today by providing an update on these products, and then discuss with you the products and product candidates that we expect to acquire or effectively in-license through the pending transactions.

Nuvion, or visilizumab, remains PDL's highest development priority. We expect to meet with the FDA in late March. At the — this end of Phase I meeting, we will discuss our plans to move Nuvion into a Phase III program. If the discussions with the FDA are positive, we hope to move into registrational trials with Nuvion in intravenous refractory — steroid refractory — ulcerative colitis late this year. We intend to use this FDA special protocol assessment process to continue to develop the protocol and plan the analysis of the Phase III program.

PDL expects to publicly update the status of its Nuvion program and the outcome of the discussion with the FDA by early April. Additional data from the Phase I/II study of Nuvion is expected to be presented during the Digestive Disease Week meeting to be held in Chicago from May 14

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through 19. We also intend to conduct pilot studies of Nuvion in patients with severe Crohn's disease and have begun the first of two pilot studies. Following our FDA discussion, we will be planning additional studies of Nuvion in patients with ulcerative colitis and expect to provide you an update of these plans in the second half of this year.

The daclizumab program has made significant progress recently. We're on schedule to begin in this first quarter a single-dose Phase I study of PDL-manufactured daclizumab administered subcutaneously. This trial will be followed by a multiple-dose study in healthy volunteers, expected to be initiated this summer. The Phase II dose range-finding study of subcutaneously administered PDL-manufactured daclizumab in asthma patients remains on schedule for the first quarter of 2006. PDL also continues to evaluate the opportunity to develop daclizumab further in the setting of solid organ transplantation. A randomized placebo-controlled, Phase II study of daclizumab in patients with multiple sclerosis is pending initiation. We just completed a successful investigator's meeting and anticipate the first patient accrual in late March or early April. In this study, patients with active relapsing forms of multiple sclerosis will receive subcutaneous daclizumab, or placebo, at one of two dosage levels for six months, in addition to their current beta interferon treatment.

The study is expected to enroll a total of 270 patients into the three treatment arms: placebo, daclizumab 2 mg/kg given every two weeks, and 1 mg/kg given every four weeks. The primary end point of this trial is MRI assessment of new gadolinium-enhancing lesions through week 24. M-200, our alpha5beta1 integrin antibody being developed as an anti-angiogenic therapy for the treatment of solid tumors, is in open-label pilot Phase II studies. These trials, each of up to 40 patients, will further assess the tolerability of prolonged administration of M200 and look for evidence of clinical activity. Two of these clinical trials are now open. The first two, a trial of M200 in combination with DTIC in melanoma, and a single agent study of M200 in renal cell cancer, are both actively accruing patients.

A third study, M200 in combination with gemcitabine in patients with pancreatic cancer, is expected to begin enrolling patients soon. And a fourth study, using M200 in combination with another agent in non-small cell lung cancer could begin in the second quarter. Based on the initial findings of these studies and the results of ongoing research experiments, additional Phase II trials may also be implemented late this year. Data from at least two of these initial Phase II studies is expected to be available for presentation during the ASCO meeting in June of 2006. M200 administered intravenously has shown activity in animal models of age related macular degeneration, or AMD. Given the attractiveness of this approach relative to intravitreal injections, we intend to proceed with the development of M200 instead of F200 for this indication.

F200, as you may know, is a fragment of the M200 antibody and was a pre-IND candidate for the intravitreal treatment of AMD. We are planning a Phase II trial of M200, administered intravenously in patients with AMD to begin during the second half of 2005. Our goal of one IND per year on average for PDL remains intact, and the next internal IND candidate in 2006 will most likely be in oncology.

As Mark said, we are very enthusiastic about transforming PDL into a fully-integrated commercial biopharmaceutical company. I would like to take some time now to review the marketed products that we'll be adding to our company with the close of the ESP Pharma and Retavase transactions.

Cardene IV is indicated for the short treatment — short-term treatment of hypertension when oral therapy is not feasible or not desirable. Cardene IV is used in the hospital as an option for the control of hypertension. It's growing rapidly in the hospital marketplace, having become a popular blood pressure control agent in acute care when oral therapy is not possible. Currently, it is used most often by neurologists, neurosurgeons, anesthesiologists, cardiologists and cardiothoracic surgeons. Increasingly, it is also used in emergency departments. We believe that given the known safety profile and efficacy of Cardene IV, the use of this agent will continue to increase as more physicians gain experience with the agent. Cardene IV is initially administered as a continuous infusion at a rate of 5 mg/hr. The infusion is then adjusted, based on the response of the patient.

Cardene IV was added to more than 100 formularies in 2004, and presently the product is on formulary in more than 95% of ESP's initially targeted institutions in the United States, and we hope to be adding further institutions to the formulary use of Cardene IV. We also will be evaluating line extension opportunities to further develop Cardene IV.

IV Busulfex is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. When used in this regimen, IV Busulfex is administered four times per day, and replaces oral busulfan, an oral formulation of the same chemical entity, for which a patient must take over 100 pills per day. Oral busulfan is associated with nausea and vomiting, and incomplete absorption that may lead to a lower drug level than was intended by the prescribing physician.

Retavase is indicated for the use in the management of acute myocardial infarction, or AMI, in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. Treatment with Retavase should be initiated as soon as possible after the onset of AMI symptoms. Retavase is used predominantly by cardiologists, cardiothoracic surgeons and emergency room physicians. PDL believes that the two bolus, fixed-dosing regimen of Retavase is an advantage in the acute setting of myocardial infarction. We are eager to begin the promotion of Retavase. Because of a significant overlap in the hospitals and physicians using both Cardene IV and Retavase, we expect our sales force to be able to capitalize on and to explore these synergies while growing the emergency room use of Cardene IV. With respect to further development opportunities for Retavase, an ongoing trial, called the Finesse Trial, is exploring the use of Retavase in combination with Reopro in the setting of facilitated percutaneous coronary intervention. The trial is being conducted by Centocor and by Eli Lilly.

While we expect the PDL pipeline will be expanded by our internal IND antibody-candidate research engine during 2006, the acquisition of ESP Pharma will bring additional development-stage compounds to our drug pipeline as well. ESP Pharma holds marketing rights for four

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development-stage compounds. Initially, following the closing, we expect to direct our efforts towards two of these compounds — terlipressin, a potential treatment for hepato-renal syndrome, or HRS, and ESP-305, a potential treatment for congestive heart failure, or CHF.

Terlipressin is a synthetic 12 amino acid peptide derived from a naturally occurring lysine vasopressin. Terlipressin is short-acting on its own, but also releases an active metabolite, lysine vasopressin, which is gradually released over several hours by the action of endogenous proteases. This gradual metabolism should lead to a reduction in vasopressor adverse effects, such as cardiac ischemia. Terlipressin causes constrictive activity in the vascular and extra-vascular smooth muscle receptors via the V-1 receptor. As a consequence, it reduces blood flow in the splanchnic area, and thereby lowers portal blood pressure. Terlipressin is approved in many European and Asian countries for the treatment of esophageal and variceal hemorrhage. These varices develop as a complication of portal hypertension in patients with liver cirrhosis. Terlipressin is not approved in the United States or Canada.

Results from early clinical trials suggest that terlipressin may have activity in patients in hepato-renal syndrome, a condition where patients with end-stage liver disease may develop progressive deterioration of renal function without a primary abnormality of the kidney. Patients who have a rapid decline of renal function, characterized as a hepato-renal symptom — syndrome type 1, have a median survival of less than two weeks. The treatment of choice for these patients is liver transplantation, but that option is not always available to all patients. There are currently no approved medical interventions for these patients.

ESP has acquired the exclusive marketing rights for terlipressin in the United States and Canada from a private U.S. company, Orphan Therapeutics, which is developing the compound in HRS. Orphan Therapeutics holds the IND and is conducting a Phase III trial in the United States and Europe. The study is a double-blind, placebo-controlled Phase III trial of terlipressin in patients with type I HRS. Patients receive either placebo or terlipressin given as one mg IV every six hours. Therapy is continued until the creatinine decreases to less than or equal to 1.5 mg/dl for at least 48 hours or for a total treatment period of 14 days. Treatment is discontinued if it fails or if the patient undergoes liver transplantation. The primary end point is assessed at day 14 in a survival in combination with the reversal of HRS as assessed by a reduction in serum creatinine. To complete the trial, at least 90 patients must be assessed at day 14. The study is open and has accrued 14 patients. Orphan Therapeutics expects to recruit additional clinical sites, so the future rate of accrual cannot be reliably assessed at this time. The rate of accrual and the number of patients evaluable at day 14 will be key factors in the timeline of the project.

We estimate that there are between 4,000 and 6,000 patients in the United States each year that could be candidates for this therapy. Orphan Therapeutics obtained orphan drug status for the program. We believe that, in addition to type I HRS, there may be other development opportunities for terlipressin. These potential additional programs could include less rapidly progressing HRS, type II, and esophageal variceal hemorrhage, among others.

The second clinical candidate from ESP Pharma that PDL intends to move forward is ESP-305, a compound for the potential treatment of congestive heart failure. ESP is a natriuretic peptide, originally called Urodilatin and now called ularitide. Ularitide is a recombinant form of this naturally occurring peptide originally isolated from human urine. Ularitide is formed from the cleavage of the same pro-hormone that produces atrial natriuretic peptide. Ularitide enhanced natriuresis and diuresis and decreased central venous pressure in a previous small study in patients with congestive heart failure. Interestingly, while not definitively shown in a randomized trial, it appears that ularitide may be associated with less worsening of renal function than has been seen with other treatment using other natriuretic peptides. Of course, the attributes would have to be shown in an adequately powered, well-controlled, randomized study.

The peptide was first isolated by scientists affiliated with the University of Hanover Institute of Peptide Research and has been developed by a German company, CardioPep Pharma. Recently, CardioPep has been conducting clinical studies of ularitide in hospitalized patients with decompensated congestive heart failure. The first of these two studies, the SIRIUS I trial, was a double-blind, placebo-controlled, ascending dose study in patients with decompensated congestive heart failure. This small trial enrolled 24 patients who received a 24-hour infusion of placebo or in ascending dose cohorts, 7.5, 15 or 30 ng/kg/min of ularitide. The study was primarily intended to assess safety, but evidence of hemodynamic activity was observed at the two higher dose levels when assessed at six hours. There was no apparent difference in adverse events across the four treatment groups. The results of the SIRIUS I trial are now in press in the American Heart Journal.

Based on these findings, CardioPep has been conducting a larger, double-blind, placebo-controlled, Phase II study of ularitide called SIRIUS II. The SIRIUS II clinical trial has enrolled a total of 221 patients. Results of this trial should become available in the second quarter of this year. Following the close of the ESP Pharma acquisition, PDL plans to work closely with CardioPep in the analysis of this trial. Top line results of the SIRIUS II trial are expected to be available in the second quarter of this year. Full presentation of the results may be possible in an appropriate scientific meeting in the fall. ESP Pharma acquired from CardioPep exclusive rights to conduct all subsequent Phase III development and exclusive marketing rights for ularitide for all indications in the United States, Canada, the European Union and Switzerland. To date, all clinical development of ularitide has taken place in Europe. The U.S. IND has not yet been filed. PDL expects to file a U.S. IND this year. In the United States alone, there are approximately 1 million hospitalizations per year for decompensated congestive heart failure.

Speaking for the entire development team, I would like to say how excited we are about these new opportunities and challenges that have been added to our plate. Particularly, we are pleased that the ESP Pharma projects will enter our pipeline at the end of Phase II or later, and that the combined pipeline will maintain a focus on hospital products while expanding PDL into cardiology. We all are very excited about not only becoming a fully integrated company, but about the broader potential of our commercial portfolio with new products that are currently in development.

I will now turn the call over to Glen Sato, our Chief Financial Officer.

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**Glen Sato - Protein Design Labs - Senior VP & CFO**

Thank you, Steve.

By now, I'm sure that you have seen our financial results for the full year and fourth quarter of 2004. In brief, I'm pleased to report that we met or exceeded our operating goals for these periods and produced financial results that exceeded consensus analyst estimates. For the full year 2004, royalty revenues grew by 59% year-over-year, \$83.8 million, and total revenues increased by 44% to \$96 million. Research and development expenses grew by 48% year-over-year to \$122.6 million, commensurate with the company's increased clinical development and manufacturing activities. Net loss for the full-year 2004 was \$53.2 million, or \$0.56 per basic and diluted share. As of December 31, 2004, we had cash, cash equivalents, marketable securities and restricted investments totaling approximately \$397.1 million, compared with \$505 million at December 31, 2003.

Looking ahead to 2005, we anticipate that, on a non-GAAP basis, our total operating revenues will be in the range of approximately \$250 to \$260 million. As a reminder, revenue amounts from the acquisition of ESP Pharma (including Retavase) are for the nine-month period beginning April 1, 2005, assuming the closing of the transaction on or about March 31.

Breaking down our revenues in somewhat more detail, of the \$250 to \$260 million projection, royalty revenues are anticipated to be in the range of \$112 to \$115 million, license and other partner-related revenues anticipated to be in the range of approximately \$20 to \$25 million and aggregate net product sales for Cardene IV, Retavase and IV Busulfex for nine months as part of PDL totaling approximately \$93 to \$95 million for our reported portion in 2005. And further breaking down the revenue detail, we also expect approximately \$25 million in off-patent brand sales for the year, although we are not providing any long-term growth projections for what we consider to be non-strategic assets. With respect to royalties, let me highlight that we received a very small royalty payment in the first quarter from fourth quarter sales of Tysabri, but our royalty revenue estimates for 2005 and beyond do not currently include further royalties based on sales of the Tysabri antibody product from Biogen Idec and Elan, which is licensed under PDL's humanization patents but was withdrawn from the market at the end of February 2005.

Overall, for the 2005 through 2008 timeframe, we anticipate compound annual growth rates of at least 25%, not only for royalty revenues, but also for net product sales for the three core products acquired as part of the ESP Pharma and Retavase acquisitions. In addition, we expect to achieve product margins in excess of 80% on net product sales of Cardene IV, Retavase and IV Busulfex in each year in the 2005 through 2008 period, which means our combined

royalty and net sales operating margins should be higher than industry average, as long as we are able to maintain these growth rates and product sales margins.

During 2005, we anticipate research and development expenses in the range of \$184 to \$186 million, of which we expect to spend over \$100 million to advance our clinical development programs for Nuvion, daclizumab and M200. We further anticipate sales and marketing expenses in the range of \$42 to \$44 million resulting primarily from the ESP Pharma acquisition and the expansion of our sales and marketing efforts with Retavase. We anticipate general and administrative expenses for the full year 2005 in the range of \$31 to \$33 million.

Overall, we currently expect a GAAP net loss for the full year 2005 in the range of approximately \$1.43 to \$1.64 per basic and diluted share, and a non-GAAP net loss in the range of \$0.18 to \$0.34 per basic and diluted share. We anticipate our year-end 2005 head count in the range of 900 to 950 full-time equivalents, split approximately 70% in research and development, 15% in sales and marketing and 15% in general and administrative functions.

We also expect capital expenditures of approximately \$38 to \$42 million during the year, approximately half of which represents final validation and completion of our new Brooklyn Park, Minnesota manufacturing facility. We expect to end 2005 with cash balances of approximately \$200 million. In addition to our overall operating loss and the capital expenditures just mentioned, this estimate takes into account anticipated cash payments during 2005 of \$325 million and \$110 million for the acquisitions of ESP Pharma and Retavase, respectively, the assumption of up to \$14 million in related debt due upon the closing of this transaction and the receipt of approximately \$240 million from the recent sale of convertible notes, net of fees and expenses.

As we have noted, the ESP Pharma and Retavase transactions have not yet closed. We do expect them to close in the next two weeks. As with any acquisitions, there are requirements to be fulfilled prior to closing and there's always some risk that the transactions will not close; however, we remain on track to close both transactions around the end of the first quarter.

At this time, let me turn the call back to Mark for additional comments.

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

Thanks, Glen. We are entering an exciting new era for PDL that I believe will be marked by an increasing focus on adding value for our shareholders and bringing needed therapies to the marketplace. As you've heard, we had a terrific year of accomplishment in 2004 that exceeded our financial and functional objectives, notwithstanding some clinical disappointments in the first half of the year.

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For 2005, we will focus on successful integration of ESP Pharma and Retavase, progressing our current pipeline on the plans we've just outlined, pushing several new programs ahead into Phase III studies, and growing total operating revenues from \$96 million in 2004 to over \$250 million in 2005. We've had some turbulent weeks in biotech leading up to this call, with some of that turbulence clearly impacting PDL royalty revenue, at least for the near-term. But as we are transforming into a commercial organization with a portfolio of marketed drugs and a proven sales force, we're going to steadily decrease our royalty dependence as we increase our own efforts focused on building hospital-based sales with novel therapies.

Excluding potential royalties payable in the event Biogen Elan's Tysabri returns to the market, we are nevertheless projecting at least 25% compound annual growth rates for the royalty stream, growing from sales of our existing seven marketed humanized antibodies from 2005 to 2008. We expect to see a matching 25% revenue CAGR from our newly-acquired marketed products from the same '05 to '08 time period. This revenue growth should make us cash flow positive in the second half of 2006; and as a result, we do not anticipate a need to come back to the capital markets to support the newly-transformed business. Our pipeline has never been deeper or more exciting, given that we have the potential to own or have rights to up to three products in Phase III by year-end 2005.

The combination of these factors, then — a proprietary and broad pipeline, growing and diversified revenues from products and royalties, and financial strength, should make us a very exciting company to watch. Thank you for your continued interest and support. I'll now turn the call over to Jim.

**Jim Goff - Protein Design Labs - Senior Director - Corporate Communications**

Thank you, Mark. That concludes the prepared presentations. Operator, please begin the Q&A.

## **QUESTION AND ANSWER**

### **Operator**

Thank you. Ladies and gentlemen, if you'd like to register a question, please press the 1 followed by the 4 on your telephone. You will hear a three-tone prompt to acknowledge your request. If your question has been answered and you'd like to withdraw your registration, please press the 1 followed by the 3. If you're using a speaker phone, please lift your handset before entering your request. One moment, please, before the first question. Our first question comes from the line of Elise Wang from Smith Barney. Please proceed with your question.

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

Thanks for taking my question. I just had a couple of questions in regards to the guidance for this year. Could you clarify what the underlying assumptions are in the number of shares that's outstanding for the year? And what might get issued under the transaction to begin with?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Let me go ahead and tell you that with respect to the acquisition of ESP, you can expect about 9.8 million additional shares to come onto the market. That would form the core of our underlying assumption for increasing share count. Obviously, there will be some options that are exercised; but fundamentally, that will form the core to the increase in share count as we go over time.

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

Okay. And then in regards to your guidance on the net loss per share, it's obviously a pretty big range. Can you just perhaps again clarify, then, what the underlying assumption is on the share count for that particular range?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

It's about 104 million — let me get you the specific number there, Elise, just a moment.

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

Okay.

**Glen Sato - Protein Design Labs - Senior VP & CFO**

It's 102.9 specifically.

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

Okay. And then can you breakdown for us the product sales for each of those — the three major products that you alluded to, obviously one of them being Retavase, in terms of the historical performance and then give us a sense of the — in terms of the forward-looking basis, obviously, you said overall 25 — at least 25 percent growth. But I'd have to think that it varies among those three. Can you give us metrics to think about in terms of the growth opportunities in each one?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Yes, Elise, let me give you the caveat. I'll give you the historical sales, specifically, but on a going-forward basis, it's not our intention to break them out unless obviously there's a reason to do that specifically under the SEC rules. So, for Retavase, the sales for 2004 were approximately \$50 million. These are net sales figures. For Cardene IV, about \$47.5 million. IV Busulfex, about \$11.9 million. And for the off-patent brands, about \$30.5 million.

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

Okay. And in regards to the license fee guidance — or the licenses and other revenue guidance of \$20 to \$25 million, what does that assume going forward here? Of the \$20 to \$25 million, what does that assume about additional deals or other kinds of payments that you might receive this year?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Well, we'll have the full year of Roche reimbursement under the asthma collaboration, as well as the continued amortization of the up-front fee during that full year. We also do have plans, as we indicated, for a deal around dac for MS. Those are really the fundamentally large drivers in that bucket. There are obviously going to be efforts in humanization and patent licenses, but those are not significant.

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

Remind me with the piece that you're amortizing for the Roche equipment deal for this year?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

The \$17.5 million up front fee —

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

Right.

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**Glen Sato - Protein Design Labs - Senior VP & CFO**

— is amortized over six years.

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

Okay.

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Your working figure should be about \$240,000 per month.

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

Okay. And just last thing for you, what are the outstanding issues in regards to closing the acquisition of ESP at this point in time?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Well, it's just that standard laundry list of conditions that have to be met. Elise, from our view, the regulatory requirements have been met, so we're really talking about going through the details of making sure, for example, that their business continues to run as originally contemplated and that they've not done anything extraordinary. There's some other things related to stockholders and the payment of severance, which are reductions in the purchase price. So, from our perspective, things are on track to be able to close in fairly short order.

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

Okay. And do you have any intentions of purchasing other drugs to support the commercial infrastructure, somewhat similar to what ESP had done?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

They are not drivers for the model, Elise. I think that the model — I think fundamentally stands on the basis of what we have here. Obviously, with the sales force, that makes us pretty well positioned to be able to consider other products. I think in the first instance, our view is to try to bring this acquisition in hand to really try to fully integrate the team and to really try to be an aggressive, fully integrated biopharmaceutical company. At that point, we will look strategically at other opportunities that present themselves, and I think we'll be pretty well positioned in those circumstances.

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

Great, okay, thank you for taking my questions.

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Thank you.

**Operator**

Thank you. Our next question comes from the line of Gil Aharon with Infinium. Please proceed with your question.

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**Gil Aharon - Infinium - Analyst**

Thank you very much for taking my call. Glen, if you can just confirm for me the acquisition of Retavase, then, \$25 million goes to the shareholders of ESP and \$110 from PDL to J&J — or through ESP?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Yes, it's technically Centocor, who's actually the owner of the rights, but yes, that's correct.

**Gil Aharon - Infinium - Analyst**

Okay. Thanks. Now, Mark, if you don't mind, if you can give us some ideas or your insight into the integration plan, of looking to bring ESP in and some of the issues with respect to the retention of ESP executives. How much of it is an issue? Or what is the plan going forward?

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

Well, it's — it's a — it's a very important issue, so you've raised a good point. We feel that the sales team, as I mentioned on the call, including the senior management team for the sales group, are being provided with a very strong multiyear retention plan, as are the additional employees in our New Jersey office that handle sales operations and the in-line marketing activities. So, we have addressed that as a really critical component, because the people behind the successful growth of ESP, we feel, are essential to successful ramping up of PDL as a commercial enterprise. Other integration elements relate to really the leadership of the site, and we've chosen who that person is and we'll talk about it after the closing.

We also have an integrated team between folks in New Jersey and folks in Fremont and our Minnesota locations to coordinate and oversee all the different critical areas of activity that support a newly commercial infrastructure. So, you know, they — one of the things PDL had never done before was sell products as an institution. Obviously, now we've gotten experienced group of people who have done that and done that very well over the past couple of years. So, we want to do everything we can to make the two organizations blend seamlessly together, and even at the board level, we'll be monitoring that during the course of 2005.

**Gil Aharon - Infinium - Analyst**

Thanks for that. And one more question, if I may, for Steven Benner, with respect to daclizumab in multiple sclerosis, I see that the trial going forward is going to have daclizumab in combination with interferon beta. And I'm not sure how much it's a clinical issue, but in light of the Tysabri incident, do you think it's more cautious to avoid combination or try single agent trial, as well?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

We're not ruling out the possibility of doing a mono therapy trial in the future, but the initial driver for doing this study is open label work that's been done with daclizumab in combination with beta interferon. Although everyone is certainly heightened in terms of the sensitivity by Tysabri, I would point out that this is a different mechanism of action so it's not clear that every combination of both biologic with Beta Interferon is going to produce the same kinds of problems. We would not want to do a mono therapy trial first in this setting, because there's a proved active agent. So first line therapy really would not be appropriate for us, given the state of our knowledge of daclizumab. So a mono therapy trial would require that we took only those patients that have truly failed Beta Interferon and other approved therapies, which would be a difficult patient population group to both identify and get enrolled into a study.



And guidance for daclizumab partnership from MS is still on for the first half of '05?

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

Yes, it is.

**Gil Aharon - Infinium - Analyst**

Thank you very much, guys.

**Operator**

Thank you. Our next question comes from the line of Matt Geller from CIBC World Markets. Please proceed with your question.

**Matt Geller - CIBC World Markets - Analyst**

Thank you. A couple of questions. First on the financial side, and then on the — and then some on the development side: First of all, on the financial side, obviously, you know, you've prepared this call — this call a little while ago. Have you included any value for Avastin for non-small cell lung cancer or would that all be upside from your guidance?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

That would all be upside from our guidance. We're pretty current, but we don't have the "ESP", so to speak.

**Matt Geller - CIBC World Markets - Analyst**

Okay, so that would be upside from the 25 percent that you've already talked about?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Yes.

**Matt Geller - CIBC World Markets - Analyst**

Now, in terms of the place of ESP-305, can you talk about how you might be positioning that drug, give that there are other drugs in development for that indication? Specifically, how you'd position it vis-à-vis Natrecor?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

Sure, what we're waiting for is the results of the SIRIUS II trial, which is a much larger trial — 221 patients — that is powered to show an improvement in activity as assessed by both a reduction of pulmonary capillary wedge pressure and an improvement in the symptom of dyspnea at six hours. So those were similar end points for the SIRIUS II, as were the basis for the approval of Natrecor. We need to see those results, obviously, before we will be able to make positioning comparisons to Natrecor, but we would anticipate that we will probably be going into a similar type of patient population.

**Matt Geller - CIBC World Markets - Analyst**

And what advantages might one have over Natrecor? What you'd be looking for in terms of its marketing edge?

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**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

Well, certainly with these agents, what you want to avoid is hypotension. And so if you're looking at the regimen, the ularitide regimen that's been developed to this point is a continuous infusion as opposed to a bolus and infusion. That, along with — that difference in regimen along with the potential differences in the agents themselves, an ANP derivative, as compared to a BMP derivative — could also have important physiologic differences. It's interesting that in patients, ularitide has never been detected in the blood, but it is found naturally as a product in the kidney.

**Matt Geller - CIBC World Markets - Analyst**

And my final question is vis-à-vis daclizumab. You talked about potential other indications. Can you talk about the potential of expanding its usage for transplantation, what the upside could be from there and what trials, you know, either ongoing, or you might have planned, for looking at additional use in transplantation?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

We think that that's potentially a very interesting opportunity. Obviously, we would like to take over the manufacturing for daclizumab from Roche to PDL using — using our new Plymouth facility in the induction setting in kidney transplant. But we think, also, that as a potential regimen that might allow us to spare calcineurin inhibitors, for example, that there might be significant potential for daclizumab in the chronic or repeated dosing setting. We've not yet

started those trials. We're in the process of building both the business case, as well as the clinical development plan, and we hope to have details for that for you in the second half of this year in terms of what we think the exact development plan will look like.

**Matt Geller - CIBC World Markets - Analyst**

Have there been trials using it chronically at all?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

There have been trials that have been sponsored by Roche that have not been done with the intent of a registration. And those trials have provided some interesting insights. Some of those trials have not yet been publicly released, so I can't discuss them; but we do think that that will give us guidance in terms of the appropriate directions for developing daclizumab.

**Matt Geller - CIBC World Markets - Analyst**

Great. Thanks a lot, and congratulations on all the progress going forward.

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

Thank you.

**Operator**

Thank you. Our next question comes from the line of Jason Zhang from Prudential. Please proceed with your question.

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**Jason Zhang - Prudential - Analyst**

Thanks. Question for Mark, you mentioned briefly the off-patent products from ESP, you might want to sell them because your guidance certainly doesn't include revenue from those products. So, are we expecting those to be — transactions to be complete pretty soon? Or how we going to deal with those products if you don't sell them? Are you going to expect to see some revenue from those products or not?

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

Well, as Glen indicated, we expect to see approximately \$25 million in off-patent revenue this year. So I don't think that any effort to sell them would be immediate. We are reviewing the opportunity for the drugs. And again, as Glen mentioned, we don't give any kind of projection as to growth rate as a consequence of that, Jason.

**Jason Zhang - Prudential - Analyst**

So that \$25 million would be offset of the \$93 to \$95 million guidance you gave for the three products, right?

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

Outside of that, yes, that's correct. In addition to that.

**Jason Zhang - Prudential - Analyst**

Okay. Okay. And — and another question is on the R&D side, certainly as compared to 2004, would be a huge increase, and could you just let us know how much of the increase is actually on the ESP side of the products, R&D, and approximate how much it will be on your own product pipeline, even if you don't do this acquisition?

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

Glen, do you want to comment?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Sure. Jason, I guess the way to think about this, if you look at the 2004 figures for what we would call the big three candidates in development — that's daclizumab, Nuvion and M200, we projected to spend about \$72.4 million for the year, and we're talking about moving into 2005 at a run rate for those big three is going to be around \$100 million. So, that's obviously going to be a fairly significant driver. I think as we also previously indicated, we are going to be manufacturing for the better part of the entire year here as we validate our commercial manufacturing facility in Minnesota. So, we had anticipated that there would, as we get ready for commercial manufacturing at approval, start to have an increase, which would flatten out — so, the bulk of the R&D spend will come from the PDL side of the house. We are still assessing the products; and while we're interested and we may, in fact, provide some spending into the ESP side of the house by virtue of their relationships with existing third parties, not a lot of that spend will hit us in 2005.

**Jason Zhang - Prudential - Analyst**

Okay, and the next question is for Steve. You know, all of a sudden, we have so many moving parts now and with regard to what to expect to hear from you — from the clinical side. And can you just — you know, for 2005, you know, right now, just kind of prioritize to us what are the major trial results or product beta points that you will want us to look at or look for?

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**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

Sure, let me give you an idea of what I think the news flow will be in the upcoming months. First, we'd expect to have a press release related to the outcome of our end of Phase I discussions relating to Nuvion. We'll take the time during that to also update you on any additional trials that may have started in that interval, as well. That will be a press release that should be issued no later than early in April. We would then follow that up in the second quarter with the announcement of at least top line — again, probably by press release — of what the SIRIUS II results are, as soon as we have those available. Those will only be top line because we will want to do a full scientific presentation of the SIRIUS II results in the fall.

Then in DDW, May 14 to 19, we will be presenting a series of abstracts, including three that directly relate to Nuvion and one that looks at sort of the epidemiology of patients with steroid resistant ulcerative colitis and one abstract at that meeting on HuZAF as well, describing our chronic dosing regimen. So that would be the next meeting where we'll have substantial data for you. Then we would anticipate that probably in the September/October timeframe, perhaps early October, we're probably going to have another R&D day to completely update everyone with regards to the status of our program. That has not been scheduled yet, but we've been in discussions about doing that, would be a way for us also then to tell you about the results — the full results — of the SIRIUS II trial, as well as our plans for Nuvion, when — when we have better clarity around the FDA process, as well. So I think those are the real highlights coming up over the next few months.

**Jason Zhang - Prudential - Analyst**

So, yes, in other words, we're not going to hear any substantial data on either M200 and Zenapax for — in 2005?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

No, I really don't think so. We're conducting the Phase I trials with daclizumab that are going — should go well. Those will — but that will take much of this year. So we won't really have new data in terms of either asthma or MS from daclizumab this year. M200 — we'll hope to have the first data from the Phase II trials that are ongoing now for ASCO in '06, not '05.

**Jason Zhang - Prudential - Analyst**

Okay. And then, finally, for Mark, this a question related to Retavase. And if you look at IMS data, the revenue has come down from 2002 to 2004. Could you let us know what has happened, you know, from what you expected and how are you going to change that? And what data do you think will enable you to do that?

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

Sure, to the extent I can answer without yet owning the rights to the product. The product, we believe, hit a peak sales in 2001 of approximately \$110 million. And that was given full and aggressive promotion by a dedicated Centocor team. Subsequent to that, the product has moved over to Scios, another J&J subsidiary that's following the acquisition of Scios by J&J because of the cardiovascular focus of that company. It's our understanding that, particularly given some other priorities at Scios, that certainly over more than the past year, the product just has not had a dedicated promotional effort behind it. Notwithstanding that, it's still got a reasonable share of the [INAUDIBLE] marketplace.

So, we feel that you're probably looking at base sales upon which we feel we can grow at a reasonable rate — not really to the level it historically used to be — but at a reasonable rate. And I think, as importantly, help us penetrate the ER for new opportunities of selling Cardene, because as Steve mentioned earlier, Cardene has a very good label, and is quite useful in a number of surgeries in the emergency room setting. And yet, we've not really had the number of reps and the product to be able to make an efficient call in that location. So now with two drugs of approximately the same size, we've made the sales force more efficient, and we think we can draw greater penetration for Cardene as a consequence.

**Jason Zhang - Prudential - Analyst**

You're saying Retavase could actually be a bait for, you know, you kind of use it as a bait for the gross potential of Cardene?

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

Well, I wouldn't call it as a bait. It allows to us call on emergency room point of contacts, because of the Retavase label, to introduce the benefits of using Cardene, because our studies before we bought the company and Retavase indicate that there was not good awareness of Cardene in most emergency rooms. So we think that's going to give us the additional opportunity to promote Cardene into those same areas.

**Jason Zhang - Prudential - Analyst**

Okay. Thanks.

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

Okay.

**Operator**

Thank you. Ladies and gentlemen, once again, as a reminder, if you'd like to queue up for a question, please press the 1 followed by the 4. Our next question comes from the line of Eric Hoffman from JP Morgan. Please proceed with your question.

**Eric Hoffman - JP Morgan - Analyst**

Thanks. Hi, guys, two questions. The first is just to clarify your guidance on net product sales, The 25 percent compound annual growth rate does not include the reacquisition of Zenapax in 2007 or any additional pipeline products such as Nuvion, terlipressin, or ESP-305?

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

That's correct, Eric.

**Eric Hoffman - JP Morgan - Analyst**

Okay. And then the second question on ESP-305, do you think that the SIRIUS II results in the second quarter of '05 and the supporting data could form the basis for an approval in Europe, at least, or would you expect additional trials?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

We believe that — that additional trials, Phase III trials, would be necessary.

**Eric Hoffman - JP Morgan - Analyst**

Okay.

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

So I think probably the best outcome for us in the event that the ESP-305, the ularitide SIRIUS II study was positive, would be to move it into Phase III.

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**Eric Hoffman - JP Morgan - Analyst**

Okay. That's great.

**Operator**

Thank you. Our next question comes from the line of George Farmer from Wachovia Securities. Please proceed with your question.

**George Farmer - Wachovia Securities - Analyst**

Hi, good afternoon. Thanks for taking my questions. Steve, could you go into the rationale for why you'd be advancing M200 as opposed to F200 in AMD? Does that reflect the competitive universe of — intravitreally administered products? Or are you actually seeing efficacy in pre-clinical models with IV administered M200?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

There's actually been efficacy in the monkey model of AMD, which it uses retinal burn to induce neovascularization. So it's the — it's the best model we have, but it's not a pure AMD model it is used as the standard in the field. But in that model, IV M200 had activity that looked very similar to intravitreal M200, and — I'm sorry, intravitreal F200. And when we look at the time to development, our belief that to come into, with a late entrant that's an intravitreal injection, which would probably be the position we would be with F200, would not be attractive, given that it's going to be much easier for the patients to be receiving repeated doses of an intravenous drug.

**George Farmer - Wachovia Securities - Analyst**

Right. Okay. Also, maybe in kind of your idea of a perfect world regarding how the FDA will get back to you regarding Nuvion, can you kind of give us what you hope to come out of those discussions?

**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

Sure. We've submitted a list of questions to the agency, asking about their interpretation of the strength of our package with regards to the clinical and CMC data. We would hope that they would agree with us for how we've outlined a registrational program and would support us moving into that program, and would also support working with us in the special protocol assessment process. So we think we should get a lot of clarity on many of those questions at our upcoming meeting.

**George Farmer - Wachovia Securities - Analyst**

Okay. Thanks. And Glen, finally, can you just remind us what — what your debt will be at the end of 20 — at the end of 2005?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

It's about — it's about, actually, at the end of 2005, 508.

**George Farmer - Wachovia Securities - Analyst**

508. Okay, and you have the first convert, when does that expire?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Well, it's not due until 2010. We have a call right in 2008.

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**George Farmer - Wachovia Securities - Analyst**

Okay, great. Thank you very much.

**Operator**

Thank you. Our next question comes from the line of Doug Fisher from Matador capital. Please proceed with your question.

**Doug Fisher - Matador Capital - Analyst**

Let me add my congratulations on your continued progress. Can you — you already touched on Retavase, but can you just talk about Cardene and IV Busulfex and the off-patent brands in terms of the growth rates that those products saw during 2004?

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

Glen, I think I can speak to that.

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Sure.

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

If I go in order that you asked, Retavase declined slightly — I don't have the exact amount, but it was a very slight decline. But I think as I mentioned, that it was tied to a dearth of promotional effort behind the program. Busulfex improved approximately 30 percent year-on-year and Cardene grew, if I'm not mistaken — Glen, help me out here — more than 35 percent, year-on-year. And as we talked about on the original conference call in announcing the ESP acquisition, Cardene has grown from a little less than \$7 million in the prior year in which ESP launched the drug, which was 2001, to last year's sales of close to \$48 million. So, it's had a fairly marked growth rate over that time period, and we think it's nicely tied — nicely correlated to the level of promotion and a very fine label within a very effective profile.

**Doug Fisher - Matador Capital - Analyst**

And these off-patent brands, have they been flat, declining — what's that been like in '04?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

They actually grew from '03 to '04. If you just know a little bit of the history, they were — some of the off-patent were acquired in 2003, so once they got into the hands to the folks at ESP, they actually did grow them. Our expectations, obviously, are not to grow them at this level. And that's just a reflection of the fact that, again, we don't consider these strategic assets for promotional efforts our part. I can elaborate a little bit also on the Cardene IV growth, because in 2003 it was \$28.5 million, and they did \$47.5 million in 2004. So very substantial growth on that front. With respect to Retavase, I believe the decline was in the range of 15 percent for the year in the same period.

**Doug Fischer - Matador Capital - Analyst**

Okay. That's very helpful. And last question, the patents on terlipressin, can you just talk a little bit about how much life is left there?

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**Steven Benner, M.D. - Protein Design Labs - Senior VP & Chief Medical Officer**

We're not prepared to talk about the patents for either ularitide or terlipressin at this time.

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

We will update that later in the year.

**Doug Fisher - Matador Capital - Analyst**

Okay, thank you.

**Operator**

Our final question is a follow-up question from the line of Elise Wang from Smith Barney. Please proceed with your question.

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

Hi, actually just a clarification question. Can you remind us, you have two converts outstanding, can you remind us the principal amount on the first and what the conversion price is? And I think you were indicating you have a call option in '08. Can you remind us what the terms are around the one that you most recently did?

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Okay, Elise, so, for the first one, which is the one we did in July of 2003, we do have our first call option in 2008. The conversion price is \$20.14. The principal amount was \$250 million. With respect to the one that we did in February just this year, again, the principal amount was \$250 million, the conversion price was \$23.69. That will not be — we don't have a call option on that until 2010, and it would not be due until 2012.

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

Okay. Thank you.

**Glen Sato - Protein Design Labs - Senior VP & CFO**

Sure.

**Operator**

Thank you. Mr. Goff, there are no further questions. I'd now like to turn the call back to you. Please continue with your presentation or closing remarks.

**Jim Goff - Protein Design Labs - Senior Director - Corporate Communications**

Thank you, operator. Before we close, I will just quickly note our schedule of upcoming presentations. Glen Sato will present PDL at the SG Cowen conference coming up this week in Boston, on March 16. Mark McDade will present at the Smith Barney Citigroup conference in

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Washington, D.C. on March 30, at the Lehman Brothers conference in Miami on April 1, and at the CIBC conference in New York City on April 4. We look forward to seeing many of you there. Thank you, everyone, and good afternoon.

**Operator**

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

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