UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (date of earliest event reported):
November 1, 2005

PROTEIN DESIGN LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-19756**	**94-3023969**
(State or other jurisdiction of incorporation)	(Commission File No.)	(I.R.S. Employer Identification No.)

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

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

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

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition

On November 1, 2005, the Company issued a press release (the "Press Release") announcing the Company's financial results for the fiscal quarter ended September 30, 2005 (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, amortization of workforce, asset impairment charge and 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.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 1, 2005, regarding the third quarter 2005 financial results of Protein Design Labs, Inc.
99.2	Transcript of earnings call, held on November 1, 2005, regarding the third quarter 2005 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: November 4, 2005

PROTEIN DESIGN LABS, INC.

By: /s/ Glen Y. Sato

Glen Y. Sato
Senior Vice President and
Chief Financial Officer

www.pdl.com

For Immediate Release

Contact:

James R. Goff
Senior Director,
Investor Relations
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jgoff@pdl.com

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PDL ANNOUNCES THIRD QUARTER 2005 FINANCIAL RESULTS

Strong revenue growth reflects addition of net product sales and increased royalties versus prior year quarter

Company increases full-year revenue guidance for marketed products and royalties

Fremont, Calif., November 1, 2005 – Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI) today reported financial results for the third quarter and first nine months of 2005. Financial highlights included:

- Third quarter net product sales of $43.1 million, an increase of 22% versus the prior quarter in 2005.
- A 52% increase in royalty revenues to $26.0 million from $17.1 million in the third quarter of 2004.
- Total costs and expenses included an asset impairment charge of $15.2 million related to the reduced value of off-patent branded products, expected to be divested, and $7.3 million for fees and milestones to collaborative partners.
- GAAP net loss of $39.4 million in the third quarter compared with a net loss of $13.6 million in the third quarter of 2004; non-GAAP net loss of $11.5 million compared with a non-GAAP net loss of $12.6 million in the 2004 third quarter.
- GAAP net loss of $126.7 million for the first nine months of 2005, compared to a $38.7 million net loss in the same period of 2004; non-GAAP net loss for the first nine months of 2005 was $5.0 million, a substantial improvement compared to the $35.7 million non-GAAP loss incurred in the first nine months of 2004.
- Total cash, cash equivalents, marketable securities and restricted investments of approximately $332.7 million as of September 30, 2005.

Mark McDade, Chief Executive Officer, PDL, said, “Our third quarter financial results are reflective of our ongoing integration of a focused, new commercial capability. We’re seeing solid combined net sales growth of our three actively marketed, recently acquired products, with both *Cardene*® and IV *Busulfex*® experiencing strong unit and dollar growth

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for the period. We have established greater presence in the hospital marketplace by adding roughly 40 sales representatives, bringing our total sales force to 105 talented individuals. Meanwhile, our partners’ success with breakthrough antibody products such as *Avastin*™, *Herceptin*® and *Synagis*® continues to grow PDL’s royalty revenues. Coupled with the positive economic impact of our new alliances with Biogen Idec, and with this morning’s announcement, Roche, we believe we are tracking well toward our stated aim of turning cash flow positive in the fourth quarter and sustainably on a full-year basis in 2006.”

Total Operating Revenues and Cash Balances:

Total operating revenues increased 288% to $76.7 million in the third quarter of 2005 from $19.8 million in the third quarter of 2004.

PDL achieved net product sales of $43.1 million in the third quarter of 2005. Of this, net sales of *Cardene*® IV, *Retavase*® and IV *Busulfex*® for the quarter totaled approximately $38.0 million, while net sales of the four off-patent branded products, marketed by PDL’s wholly-owned subsidiary, ESP Pharma, Inc., were approximately $5.1 million for the quarter.

Royalty revenues increased 52% to $26.0 million, compared with royalty revenues of $17.1 million in the third quarter of 2004. PDL currently receives royalties based on worldwide net sales of seven antibody products licensed under PDL’s antibody humanization patents: *Avastin*™, *Herceptin*®, *Xolair*® and *Raptiva*® from Genentech, Inc.; *Synagis*® from MedImmune, Inc.; *Mylotarg*® from Wyeth and Zenapax®, marketed by Roche. License and other revenues increased 184% to $7.5 million, compared with $2.7 million in the comparable quarter of 2004, primarily as a result of revenue recognized under the new Biogen Idec collaboration.

Cash, cash equivalents, marketable securities and restricted investments totaled approximately $332.7 million as of September 30, 2005. The September 30, 2005 balances include a $40.0 million upfront payment from Biogen Idec and proceeds of the sale of approximately 4.0 million shares of common stock to Biogen Idec of approximately $100 million, related to the companies’ collaborative agreement for the co-development, manufacture and commercialization of three Phase II antibodies.

Costs and Expenses:

The cost of product sales was $22.2 million in the third quarter of 2005. Excluding non-cash amortization of product costs associated with the purchases of ESP Pharma and *Retavase*, pro forma cost of product sales was $10.3 million. Selling, general and administrative expenses increased to $26.8 million, compared to $7.7 million in the third quarter of 2004, primarily due to sales expenses associated with PDL's newly acquired and growing sales team as well as the initiation of new *Retavase* promotional efforts late in the third quarter of 2005.

Research and development expenses increased to $49.5 million in the third quarter of 2005, compared with $27.3 million in the same three months of 2004. The third quarter 2005 research and development expenses include expenses of $42.2 million consisting of increased clinical trial efforts, manufacturing-related efforts and planned growth in personnel in these areas. In addition, research and development expenses

included approximately $7.3 million of fees and milestone payments related to product-related assets and new technology. These payments included roughly $6.0 million related to the acquisition of additional commercial and development rights for ularitide and milestone payments to partners for continued successful clinical development of ularitide and terlipressin.

Total costs and expenses were $113.7 million in the third quarter of 2005, compared with $35.0 million in the third quarter of 2004, reflecting the full integration of ESP Pharma and *Retavase*, and support of wholly new marketing efforts. Total costs and expenses in the third quarter included a $15.2 million impairment charge related to a revaluation of the off-patent branded products acquired as part of the ESP Pharma acquisition; a sale of these off-patent branded products is expected to be concluded during the fourth quarter of 2005. On a non-GAAP basis, total costs and expenses in the 2005 third quarter were $85.9 million compared to non-GAAP expenses of $34.0 million in the third quarter of 2004.

For the nine months ended September 30, 2005, GAAP total costs and expenses were $317.5 million compared with $115.5 million for the comparable 2004 period, and non-GAAP total costs and expenses were $195.8 million compared with $112.6 million for the comparable 2004 period.

Note: Non-GAAP results for the three- and nine-month periods reported exclude certain non-cash charges, which consisted primarily of an acquired in-process research and development charge in the first quarter of 2005 related to the ESP Pharma acquisition, an asset impairment charge related to the off-patent branded products as well as the amortization of intangible assets associated with the Eos Biotechnology, Inc. and ESP Pharma and *Retavase* acquisitions and the re-acquisition of rights to manufacture and market Zenapax® (daclizumab) in 2003, and stock-based compensation charges. Reconciliations of GAAP results to non-GAAP results for periods presented are included in the tables accompanying this release. The forward-looking guidance set forth in the 2005 full-year guidance discussion below excludes certain non-cash charges identified above based on current estimates for the full year as follows: $79.4 million for an acquired in-process research and development charge; $15.2 million asset impairment charge for off-patent branded products; $39.0 million for amortization of intangible assets; and $1.0 million in stock compensation charges. In total, these adjustments are expected to reduce the GAAP reported operating loss by approximately $134.6 million.

Full-year 2005 Forward-looking Guidance:

The following statements are based on current expectations as of November 1, 2005, and PDL undertakes no obligation to update this information. These statements are forward-looking and do not include the potential impact of additional collaborations, material licensing arrangements or other strategic transactions.

- PDL now anticipates that total operating revenues for 2005 will be in the range of approximately $266 to $282 million.
    - For the approximately nine-month period of sales following the close of the acquisition of ESP Pharma in March 2005, net product sales for *Cardene*® IV, *Retavase*® and IV *Busulfex*® are expected to total approximately $108 to $113 million. PDL reaffirms previously guided compound annual growth

rates of approximately 25% for net product sales of this group of products for each year from 2006 through 2008.

- Royalty revenues are expected to be in the range of approximately $125 to $130 million, and license and other revenues are expected to fall in a range of approximately $25 to $30 million, including approximately $20 million in reimbursements and payments from Roche and Biogen Idec under our collaborative arrangements. PDL reaffirms our previously stated guidance that royalty revenues for each year from 2006 through 2008 should grow at least 25% per year on a compounded basis.
- PDL expects to divest the off-patent branded products, and their expected contribution to net product sales for the remainder of the year is minor. Guidance for full-year sales has been reduced to $8 to $9 million for 2005.

- PDL continues to anticipate gross margins on a non-GAAP basis of approximately 80% for *Cardene* IV, *Retavase* and IV *Busulfex* over the 2005 through 2008 period.
- Non-GAAP expenses are anticipated to be as follows: cost of product sales is expected to total approximately $26 million; research and development expenses are anticipated to be in a range of approximately $163 to $168 million; and selling, general and administrative expenses for the full year 2005 are expected to be in a range of $78 to $80 million.
- For the full year 2005, PDL anticipates a GAAP net loss in the range of approximately $1.26 to $1.38 per basic and diluted share, and on a non-GAAP basis, in a range from net income of $0.03 cents to a net loss of approximately $0.04 cents per share. Per share basic calculations are anticipated to be based on a weighted average of approximately 103 million shares outstanding for the year. Quarterly results are expected to

continue to vary due to some seasonality in the sales of certain royalty-bearing products. PDL reaffirms our expectation of positive cash flow for the fourth quarter of 2005, and on a full-year basis for 2006.

- PDL estimates that its year-end 2005 cash balances will be approximately $350 million.

- PDL expects that headcount at year-end 2005 will be approximately 975, at the high end of previous guidance as additional headcount are added to support collaborations and clinical development of the pipeline, in particular in preparation for the first half of 2006 and the planned initiation of potentially pivotal studies for *Nuvion*® and completion of the Phase III study of terlipressin.

Webcast:

PDL will webcast a conference call live at 4:30 p.m. Eastern time today to review its financial results for the third quarter ended September 30, 2005, the status of its clinical development programs 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*.

Please connect to this website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast. The webcast will be archived at *www.pdl.com* starting approximately one hour after completion of the webcast. A replay of the conference call will also be available by telephone from approximately 6:30 p.m. Eastern time on November 1, 2005 through 6:30 p.m. Eastern time on November 6, 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 21266718.

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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, in the forward-looking statements. The forward-looking statements include our expectations regarding financial results, our expectations regarding the continuation of existing and new collaborative agreements, the possibility that the off-patent branded products will be sold and the anticipated sale price for those products, 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 continued successful integration of ESP Pharma and *Retavase* as part of PDL, including the retention of the sales force; changes in our development plans as we and our collaborators consider development plans and alternatives; factors affecting the clinical timeline such as enrollment rates and availability of clinical materials; fluctuations in sales that may result from our integration of newly acquired operations; changes in the market due to alternative treatments or other actions by competitors; and 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, including in particular the continued success of *Avastin* and *Herceptin* antibody products by Genentech, Inc. 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 agreements with Biogen Idec and Roche. Our net income will be affected by state and federal taxes, and our revenues and expenses would 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. Other factors that may cause our actual results to differ materially from those expressed 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:

PDL is a biopharmaceutical company focused on the research, development and commercialization of novel therapies for inflammation and autoimmune diseases, acute cardiac conditions and cancer. PDL markets several biopharmaceutical products in the

United States through its hospital sales force and wholly-owned subsidiary, ESP Pharma, Inc. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products. Further information on PDL is available at *www.pdl.com*.

Financial tables attached

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

(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Revenues:				
Product sales, net	$ 43,144	$ —	$ 79,437	$ —
Royalties	26,003	17,131	96,695	63,872
License and other	7,536	2,653	17,127	9,323
Total revenues	76,683	19,784	193,259	73,195
Costs and expenses:				
Costs of product sales	22,209	—	43,481	—
Research and development	49,480	27,326	125,080	92,364
Selling, general and administrative	26,795	7,664	54,267	23,182
Asset impairment charge	15,225	—	15,225	—
Acquired in-process research and development	—	—	79,417	—
Total costs and expenses	113,709	34,990	317,470	115,546
Operating loss	(37,026)	(15,206)	(124,211)	(42,351)
Interest and other income, net	2,027	2,822	6,835	7,689
Interest expense	(2,671)	(1,193)	(7,522)	(3,929)
Loss before income taxes	(37,670)	(13,577)	(124,898)	(38,591)
Provision for income taxes	1,680	12	1,767	68
Net loss	$ (39,350)	$ (13,589)	$ (126,665)	$ (38,659)
Basic and diluted net loss per share	$ (0.37)	$ (0.14)	$ (1.24)	$ (0.41)
Shares used in computation of basic and diluted net loss per share	105,272	95,196	101,910	94,771

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

We use non-GAAP amounts that exclude certain non-cash charges, including amounts related to the amortization of intangible assets, asset impairment charge and stock-based compensation. Management believes that these non-GAAP measures enhance an investor's overall understanding of our financial performance and future prospects by reconciling more closely to the actual cash expenses of the Company in its operations. Our managment uses these non-GAAP financial measures in evaluating the Company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)

	Three months ended September 30,					
	2005			2004		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Product Sales	$ 43,144		$ 43,144	$ —		$ —
Royalties	26,003		26,003	17,131		17,131
License and other	7,536		7,536	2,653		2,653
Total revenues	76,683		76,683	19,784		19,784
Costs and expenses:						
Cost of Product Sales	22,209	$ (11,907)	10,302			
Research and development	49,480	(554)	48,926	27,326	$ (958)	26,368
Selling, general and administrative	26,795	(118)	26,677	7,664	(14)	7,650
Asset impairment charge	15,225	(15,225)	—			
Total costs and expenses	113,709	(27,804)	85,905	34,990	(972)	34,018
Operating loss	(37,026)	27,804	(9,222)	(15,206)	972	(14,234)
Interest and other income, net	2,027		2,027	2,822		2,822
Interest expense	(2,671)		(2,671)	(1,193)		(1,193)
Loss before income taxes	(37,670)	27,804	(9,866)	(13,577)	972	(12,605)
Provision for income taxes	1,680		1,680	12		12
Net loss	$ (39,350)	$ 27,804	$ (11,546)	$ (13,589)	$ 972	$ (12,617)
Net loss per basic and diluted share:	$ (0.37)		$ (0.11)	$ (0.14)		$ (0.13)
Shares used in computation of net loss	105,272		105,272	95,196		95,196

per basic and diluted share:						

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

We use non-GAAP amounts that exclude certain non-cash charges, including amounts related to the amortization of intangible assets, asset impairment charge and stock-based compensation. Management believes that these non-GAAP measures enhance an investor's overall understanding of our financial performance and future prospects by reconciling more closely to the actual cash expenses of the Company in its operations. Our managment uses these non-GAAP financial measures in evaluating the Company's operating performance and for budgeting and planning purposes.

(In thousands, except per share data)

	Nine months ended September 30,					
	2005			2004		
	GAAP	Adjustment	Non-GAAP	GAAP	Adjustment	Non-GAAP
Revenues:						
Product Sales	$ 79,437		$ 79,437	$ —		$ —
Royalties	96,695		96,695	63,872		63,872
License and other	17,127		17,127	9,323		9,323
Total revenues	193,259		193,259	73,195		73,195
Costs and expenses:						
Costs of product sales	43,481	$ (24,870)	18,611			
Research and development	125,080	(1,721)	123,359	92,364	$ (2,954)	89,410
Selling, general and administrative	54,267	(428)	53,839	23,182	(42)	23,140
Asset impairment charge	15,225	(15,225)	—			
Acquired in-process research and development	79,417	(79,417)	—	—		—
Total costs and expenses	317,470	(121,661)	195,809	115,546	(2,996)	112,550
Operating loss	(124,211)	121,661	(2,550)	(42,351)	2,996	(39,355)
Interest and other income, net	6,835		6,835	7,689		7,689
Interest expense	(7,522)		(7,522)	(3,929)		(3,929)
Loss before income taxes	(124,898)	121,661	(3,237)	(38,591)	2,996	(35,595)
Provision for income taxes	1,767		1,767	68		68
Net loss	$ (126,665)	$ 121,661	$ (5,004)	$ (38,659)	$ 2,996	$ (35,663)
Net loss per basic and diluted share:	$ (1.24)		$ (0.05)	$ (0.41)		$ (0.38)
Shares used in computation of net loss per basic and diluted share:	101,910		101,910	94,771		94,771

CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

(In thousands)

	September 30, 2005	December 31, 2004*
Cash, cash equivalents, marketable securities and restricted investments	$ 332,678	$ 397,080
Total assets	1,176,127	713,732
Total stockholders' equity	551,974	412,510

*Derived from the December 31, 2004 audited consolidated financial statements.

CONSOLIDATED STATEMENT OF CASH FLOW DATA
(Unaudited)

(In thousands)

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss	$ (39,350)	$ (126,665)
Adjustments to reconcile net loss to net cash provided by operating activities	42,540	144,631
Changes in assets and liabilities	28,452	11,252

Net cash provided by operating activities	$ 31,642	$ 29,218

FINAL TRANSCRIPT
PDLI - Q3 2005 Protein Design Labs Earnings Conference Call

Event Date/Time: Nov. 01. 2005 / 4:30PM ET
www.streetevents.com Contact Us

C O R P O R A T E P A R T I C I P A N T S
Jim Goff
Protein Design Labs Inc. - Senior Director, IR
Mark McDade
Protein Design Labs Inc. - CEO
Glen Sato
Protein Design Labs Inc - CFO
Steven Benner
Protein Design Labs Inc. - Chief Medical Officer

C O N F E R E N C E C A L L P A R T I C I P A N T S
Matt Geller
CIBC - Analyst
Elise Wang
Citigroup - Analyst
Joel Sendek
Lazard Capital Markets - Analyst
Gil Aharon
Infinium Capital - Analyst
Jason Zhang
Prudential Equity - Analyst
Tom McGahren
Merrill Lynch - Analyst
Jennifer Chao
Deutsche Bank – Analyst

P R E S E N T A T I O N
Operator
Welcome to the Protein Design Labs third quarter 2005 earnings conference call. Afterwards, we will conduct a question and answer session. As a reminder, this conference is being recorded November 1, 2005. I would now like to turn the conference over to Jim Goff, Senior Director, Investor Relations. Please go ahead, sir.

Jim Goff - *Protein Design Labs Inc. - Senior Director, IR*
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'll provide an overview of recent clinical and corporate highlights, review PDL's third quarter 2005 results, and update our financial guidance for 2005. As usual, we'll provide sufficient time following our comments for questions and answers. During Q & A, we request that you limit yourself to one question so that others also can participate. We'll try to take additional questions from you later in the call, should time permit. As we begin, let me remind you that the information that 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 & Exchange Commission. I'll now turn the call over to Mark McDade, Chief Executive Officer.

Mark McDade - *Protein Design Labs Inc. - CEO*
Thanks, Jim, and thanks to all of you for joining today's third quarter conference call. I'll begin with an overview of third quarter and nine-month highlights. Glen will then discuss our third quarter results and our updated forward-looking guidance. And finally, Steve Benner will provide a very brief update of our priority clinical efforts, abbreviated since we held an R&D update early last month.

Last quarter, we outlined our near-term emphasis for building this dynamic biopharma company, soon to be renamed PDL BioPharma. Central to our advancing — to advancing our business, our growing revenues, integrating the organization, and turning cash flow positive as soon as it's sustainable. We also discussed building an even deeper and more exciting biotech pipeline, funded, in part, by strong global partners like Roche and Biogen Idec, both of which are committed to shared development and commercialization of novel biologic products. In fact, as you've probably seen in the announcement earlier today, Roche has agreed to yet again expand our Daclizumab collaboration, by adding a new 50/50 expense and profit-sharing relationship aimed at the development and commercialization of Daclizumab in a potential indication of transplant maintenance. We will receive an up-front payment of $10 million and may receive potential milestone payments of up to $145 million. We have also waived our option to re-acquire rights in the acute transplant setting, and therefore have agreed that we will not pay the approximate $20 million option exercise fee for Zenapax. This marks the third major collaboration formed around Daclizumab since we purchased it back from Roche in October of 2003, and we are obviously more excited than ever about the potential for this important humanized antibody.

Our strong third quarter revenue show the progress we've made in our first six months as a commercial organization, with a very clear emphasis on the sales of Cardene IV, Retavase and IV Busulfex. We've enabled to integrate and grow our newly acquired sales organization, while continuing to increase product revenues, and have built a new tactical marketing team around the support of our three key brands. During the third quarter, we reached our goal of building a team of 105 sales representatives, through a combination of external growth, as well as a very high level of retention of our talented sales representatives and

management team. As a result, we've made significant inroads in penetrating additional hospitals in the marketplace, and in part, this has resulted in our increased product net sales in both units and dollars.

The signing of the Biogen Idec collaboration in August fulfilled two of our 2005 corporate partnering objectives, the first for Daclizumab and MS, and the second which used that for cross all indications. Biogen Idec's overall support better enables advancement of Daclizumab MS, M200 and cancer, and HuZAF in rheumatoid arthritis and Crohn's disease, more effectively than we had been able to do alone. In combination with our newly-expanded Roche collaboration, from our view, these two partnerships significantly augment our ability to push multiple later-stage programs ahead. In addition to our newly-acquired net sales revenue, we continue to benefit from the continued success of our licensees, Genentech, MedImmune, Wyeth and Roche, whose breakthrough antibody products are driving double-digit growth of PDL's royalty revenues. As a result of this improved top line performance, I am pleased to say that we have again increased revenue guidance for the full year 2005 to a top line of up to $282 million. Last quarter, we said we expected PDL to be cash flow positive in the fourth quarter of this year, and cash flow positive on a full-year basis for 2006, as well as sustainably annually in subsequent years. We are re-affirming this guidance today due to strong revenue growth from products and royalties, as well as the creative impact of our new alliances with both Biogen Idec and the newest Roche relationship. We believe this shows dramatic progress in the right direction, while we simultaneously expand research and development funding, so essential to a deepening and later-stage pipeline.

On October 7, we provided a detailed summary of the status and plans for our clinical programs, and Steve will recap the highlights from this meeting shortly. We also noted during our recent R&D update that we anticipate initiating a Phase I study in late 2006 of a new humanized antibody in the setting of multiple myeloma, representing our follow-through on our commitment to enter at least one new antibody product per year into clinical trials. These overall efforts are not feasible without significant increases in both external spending, as well as new internal personnel and expenditures. Consequently, we've continued to increase our overall research and development spending, and in particular this past quarter, we also invested just over $7 million in product-related assets and new technology, which we believe will lead to future commercial success and a richer pipeline. Our ability to make such investments, even while heading toward positive cash flow annually, should be reassuring to our shareholders. I'd now like to turn the call over to our Chief Financial Officer, Glen Sato, for a discussion of our third quarter financial results, as well as our updated guidance for the full year 2005.

Glen Sato - *Protein Design Labs Inc - CFO*
Thanks, Mark. Our third quarter results were characterized by continued strong operating revenue growth, exceeding expectations for all key revenue components: net product sales, royalties, and license and other revenues, which consisted primarily of reimbursements under collaborative alliances. Directionally, we are still on track to become cash flow positive in this fourth quarter, and sustainably on an annual basis beginning with full year 2006. In the third

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quarter, we grew the top line very substantially through a well balanced increase in product and royalty revenues. Total operating revenues increased 288% to $76.7 million in the third quarter of 2005, compared to $19.8 million in the third quarter of 2004.

As a result of our ESP Pharma and Retavase acquisitions, PDL recognized net product sales revenues of $43.1 million in the 2005 third quarter. This operating revenue reflects product sales primarily in four areas: first, this is our second full quarter of net sales of Cardene IV, which is indicated for the short-term treatment of hypertension when oral therapy is not feasible or desirable; second, Retavase, used to dissolve coronary blood clots and improve blood flow in heart attack patients; third, IV Busulfex, a conditioning agent used in connection with bone marrow transplants in chronic myelogenous leukemia; and finally, four off-patent branded products. All are marketed by PDL's wholly-owned subsidiary ESP Pharma. Net product sales for Cardene, Retavase and Busulfex, as a group, totalled approximately $38 million, while sales of the off-patent branded products were about $5.1 million. We are particularly pleased with the sales results of our three propriety products, as the level of sales in the channel has been reduced to less than half of the levels prior to our acquisition of these products. This brings us more in line with industry standards, and with our estimates of end user demand as reflected in NDC data for sales for these products.

Total operating revenue growth also included a 52% increase in royalties, which were $26 million, compared with royalty revenue of $17.1 million in the same quarter last year. As many of you know, PDL receives royalties based on worldwide net sales of seven antibody products licensed under our antibody humanization patents. Four of them are licensed by Genentech, and those are: Avastin, Herceptin, Xolair, and Raptiva. We also receive royalties on Synagis, from MedImmune; Mylotarg from Wyeth; and Zenapax, which is marketed by Roche. License and other revenues increase increased 184% to $7.5 million compared, to $2.7 million in the same quarter of 2004, primarily as a result of revenues recognized under the new Biogen Idec collaboration.

Turning to the expense side, the cost of product sales was $22.2 million in the third quarter, compared with none in the comparable period of 2004, reflecting the addition of ESP Pharma and Retavase in March, 2005. Excluding non-cash amortization of product costs of $11.9 million associated with the purchase of ESP Pharma and Retavase, cost of product sales was $10.3 million. Selling, general, and administrative expenses increased to $26.8 million, compared to $7.7 million in the third quarter of 2004, primarily due to sales and marketing expenses associated with PDL's new sales and strategic marketing teams. Research and development expenses increased to $49.5 million in the third quarter of 2005, compared with $27.3 million in the same three months of 2004. The third quarter 2005 research and development expenses included expenses of $42.2 million, consisting of increased clinical trial efforts, manufacturing-related efforts, and planned growth in personnel in these areas. Third quarter R&D expenses also included $7.3 million in fees and milestone payments. These primarily consisted of approximately $6 million related to the acquisition of additional commercial and development rights for Ularitide, for which we now own all development and commercial rights in all indications worldwide, as well as milestone payments to our partners for continued successful clinical development of Ularitide and Terlipressin. The remaining $1.3 million was for access to technology and licenses in support of new collaborations and research initiatives.

Total costs and expenses were $113.7 million in the third quarter of 2005, compared with $35 million in the third quarter of 2004. Total costs and expenses in the third quarter included a $15.2 million impairment charge related to a re-valuation of the off-patent branded products acquired as part of the ESP Pharma acquisition, that are pending sale in the fourth quarter. Specifically, net sales of these products have not met our expectations, and our estimate of proceeds from the potential sale is currently lower than our allocated purchase price from the ESP Pharma acquisition. As a result, we have reduced the value of these four products with our $15.2 million charge in the quarter.

A non-GAAP basis, total cost and expenses in 2005 third quarter were $85.9 million, compared to non-GAAP expenses of $34 million in last year's third quarter. Clearly, this increase is a result of our acquisition of ESP Pharma and Retavase, which, combined with PDL, have now resulted in a fully-integrated biopharma company. Please note that non-GAAP results for 3 and 9-month periods reported exclude non-cash charges, which consisted primarily of an acquired in-process research and development charge in the first quarter of 2005, related to the ESP Pharma acquisition; an asset impairment charge related to the off-patent branded products; as well as the amortization of intangible assets associated with the Eos Biotechnology, and ESP Pharma, and Retavase

acquisition; as well as the re-acquisition of rights to manufacture and market Zenapax Daclizumab in 2003; and some stock-based compensation charges. Reconciliations of GAAP to non-GAAP results are included in the tables accompanying today's press release, and are available at our website, *www.pdl.com*.

Now, let's turn to guidance for financial and operating results for the full year 2005. PDL anticipates that total operating revenues for 2005 will be approximately 266 to $282 million. Net product sales for Cardene IV, Retavase, and IV Busulfex are expected to total in the range of 108 to $113 million for the approximately 9-month period of sales following the close of the ESP Pharma acquisition. We reiterate our expected compound annual growth rate of approximately 25% for net product sales of this product group for each year from 2006 through 2008. PDL continues

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to anticipate gross margins on a non-GAAP basis of approximately 80% for this product group for this same period. The current estimate for net product sales of off-patent branded products for the year has been reduced to the range of 8 to $9 million. We have reduced our guidance due to disappointing 9-month net sales levels of these products, and we expect to divest them in the fourth quarter. As we have stated in the past, we continue to view these products as non-strategic assets, and their contribution to net product sales for the remainder of the year will be minor.

Our royalty revenue guidance for 2005 is increased to a range of approximately 125 to $130 million, up approximately $5 million for the entire range. PDL continues to believe that the compound annual growth rate for royalty revenue for each year from 2006 through 2008 will be at least 25%. This guidance does not assume any new licensed antibody approvals. Our guidance for license and other revenue is increased slightly from prior guidance, to a range of approximately 25 to $30 million, including approximately $20 million in reimbursements and payments from Roche and Biogen Idec under our collaborative arrangements. These amounts represent the amortization of the up-front fees from Roche for the asthma and transplant collaboration; and Biogen Idec for our multi-product development arrangement, as well as reimbursement amounts for the respective share of PDL development costs incurred for the year.

On a separate note, as an update from our August 4 earnings call, we understand that the accounting guidance authorities have been requested to review whether reimbursement funding should be treated on a so-called gross, i.e. revenue recognized for reimbursement of expenses, as currently specified under GAAP or on a net basis. In the absence of further guidance on this topic, we continue to report reimbursement amounts on a gross basis in accordance with GAAP as we have for the year, and will advise our investors of any changes if new guidance is forth-coming.

Turning now to our updated full-year guidance on the expense side, our guidance is as follows: non-GAAP cost of product sales is expected to total approximately $26 million, adjusted slightly higher, primarily to reflect increased costs associated with our Retavase product. Research and development expenses are anticipated to be in the range of approximately 163 to $168 million, unchanged from our previous guidance of August 4. Selling, general, and administrative expenses for the full year 2005 are expected to be in the range of 78 to $80 million, somewhat higher than prior guidance due to our rapid success in completing our sales force hiring target, and the related implementation of strategic marketing initiatives.

For the full year 2005, PDL anticipates a GAAP net loss in the range of approximately $1.26 to $1.38 per basic and diluted share, increased primarily due to the $15.2 million impairment charge in the third quarter. On a non-GAAP basis, we expect financial results to range from a net loss of approximately $0.04 per basic and diluted share, to net income of approximately $0.03 per share, based on a weighted average of approximately 103 million basic shares outstanding for the year. We continue to estimate that our year-end 2005 cash balances will be approximately $350 million. Of this, $140 million is from the up-front payment and the equity purchase components of our new alliance with Biogen Idec.

PDL expects that head count at year end 2005 will be approximately 975 full-time employees, or at the higher end of our prior guidance. We note that for reconciliation to GAAP, our forward-looking full-year 2005 guidance excludes certain non-cash charges based on our current estimates for the full year that are as follows: $79.4 million for an acquired in-process research and development charge; $15.2 million for an asset impairment charge for off-patent branded products; $39 million for amortization of intangible assets; and $1 million in stock compensation charges. In total, these adjustments are expected to reduce the GAAP reported operating loss by approximately $134.6 million.

Overall, we believe the operational results for the third quarter and first nine months of 2005 indicate that we're on track to transform PDL sustainably cash flow positive on a full-year basis in 2006. Future quarterly results may vary due to seasonality and the sales of royalty-bearing products. As a consequence, and due to the somewhat variable nature of our business from quarter to quarter, and particularly the timing of expenses, such as the R&D expenses for license and milestone fees, and clinical expenses, which are a function of clinical accrual, for the foreseeable future, we do not expect to provide financial guidance broken out into a quarterly format. At this time, I'd like to turn the call over to our Chief Medical Officer, Dr. Steven Benner.

Steven Benner - *Protein Design Labs Inc. - Chief Medical Officer*
Thanks, Glen. I was pleased to host on October 7, PDL's second annual Research and Development Update in New York. During that meeting, we reviewed the current status of each of our development programs, and the development plans for the three products we believe are closest to market. Here are the important highlights summarized from that meeting.

Terlipressin, a vasopressin analog, has both an orphan drug and fast track designation as a potential therapy for type 1 hepatorenal syndrome. An ongoing Phase III clinical trial is being conducted by our partner, Orphan Therapeutics.

Approximately 120 patients are expected to be enrolled. We intend to complete enrollment by the fourth quarter of 2006. To date, over half the patients have been accrued, and as the pace of accrual has picked up, it may be possible to complete the trial earlier.

For Nuvion, or visilizumab, our humanized anti-CD3 antibody, in development for the treatment of IV steroid refractory ulcerative colitis, we're on track to begin enrollment in a pivotal Phase II/III trial by the first quarter of 2006. Pilot studies in Crohn's disease are also ongoing.

Ularitide, a natriuretic peptide, derived from the prohormone of ANP, has been studied in two Phase II trials. The second, larger Phase II trial, Sirius ll, met the primary endpoints, and was presented at both the European Society of Cardiology meeting on September 4 in Stockholm, and at the Heart Failure Society of America meeting in Florida in mid-September. We also plan to release additional analyses from this study at the forthcoming American Heart Association meeting, taking place this year in Dallas on November 14. Clinical studies to date have been conducted in Europe by CardioPep, a small German biotechnology company and the originator of the compound. We plan to file an IND in the United States by the end of 2005 or very early in 2006, and to initiate a Phase IIb clinical trial during the first quarter of 2006, for which we expect to enroll patients from centers in the U.S., Europe, Israel, and Australia. This study is expected to use a composite endpoint, including a physician's global assessment, patient assessment of dyspnea, and a need for co-intervention.

We expect that [mortality] be a secondary endpoint. Patients will be followed for six months. Separately, we intend to discuss with the European Agency for the Evaluation of Medicinal Products, the EMEA, the possibility of using data from a single Phase III study as the basis of a marketing approval in European Union, using the scientific advice procedure. That Phase III study is expected to begin in the second half of 2006.

For Daclizumab, our anti-IL-2 receptor antibody, a multiple dose study of subcutaneously administered, PDL-manufactured Daclizumab in healthy volunteers is ongoing, part of our overall plan with Roche in asthma. The next step in patients with chronic persistent asthma, will be a Phase IIb dose range finding study, using Daclizumab administered subcutaneously. We're on track to begin this study in collaboration with Roche in the first quarter of 2006. In addition, earlier this year we initiated a Phase II study of Daclizumab in patients with relapsing, remitting multiple sclerosis. This trial is expected to enroll approximately 270 patients, and is evaluating Daclizumab as an add-on therapy to beta interferon. Our future plans for new transplant maintenance efforts will be disclosed in 2006, once we and our new partner, Roche, fully refine and agree on our next steps.

For Volociximab, also known as M200, an anti-angiogenic antibody that binds to the alpha5beta1 integrin, we anticipate that the first public release of data from at least two of the ongoing Phase II studies in solid tumors, will be around the town of the ASCO meeting in the second quarter of 2006. Overall, during 2005, I believe we've continued to make great strides in advancing our multiple clinical stage programs, which address a number of important unmet medical needs. In addition, our collaboration with Roche and Biogen Idec are facilitating broader and more rapid study of three of our Phase II programs, which also allows our growing team to focus on our three most advanced programs: Terlipressin, Nuvion, and Ularitide. I'll now turn the call back to Mark.

Mark McDade - *Protein Design Labs Inc. - CEO*
Thank you, Steve. I'd like to first thank Glen Sato for his multiple years of service with PDL, as heads off to join the life scientist group of as-yet-undisclosed, but highly respected law firm. Earlier, as an attorney, and more recently as our Chief Financial Officer, Glen has contributed in many important ways to PDL's recent progress and successes. From all of us at PDL, our thanks.

I also wanted to recap what I believe you should take away from our third quarter performance. First, total net product sales of our three proprietary branded products, Cardene IV, Retavase, and IV Busulfex, have grown significantly for the second straight quarter, and we believe this is reflected in demand, not a channel-filling artifact. Second, these growing product sales, combined with continued rapid growth of royalties, in partner-related fees and payments, have boosted quarterly sales by almost 300% versus the prior year, same quarter. Third, while our operating expenses have also grown significantly, the majority of this growth is due to essential sales and marketing expenses, as well as ongoing investments necessary for developing a deeper pipeline. Fourth, we are maintaining a sharp focus on moving our pipeline forward in later clinical studies, with our second pivotal program, Nuvion, expected to commence the first of two registration related trials by the first quarter of 2006. And Ularitide, perhaps our most exciting later-stage program, is planned for pivotal initiation in Europe in the second half of 2006. Even with all of this progress, we have finished the first nine months of this year only a nickel per share in the red on a non-GAAP basis. We believe that's the kind of forward progress and trend line toward a positive cash flow that has resulted from our steady aim over the past three years.

On the business front, for the first time ever this coming April, 2006, we plan on holding an update for the financial community to review the status of our marketed products, including Cardene IV, Retavase and IV Busulfex, as well as discuss the opportunities we see for a more advanced pipeline programs. The meeting will also give us a chance to

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describe our plans to expand into new indications for our marketed drugs. Near-term and next January's JPMorgan conference, I look forward to joining you where we'll be unveiling our new 5-year plan, vision 2010, and our new name of PDL Biopharma, as part of the our communications effort early in the new year. Needless to say, we're excited about our prospects, and thankful to all our partners, our collaborators, our advisors, our employees, and our shareholders, for helping us build PDL. With Thanksgiving just ahead, I wish all of you a peaceful and thoughtful holiday season. Now let me turn the call back over to Jim.

Jim Goff - *Protein Design Labs Inc. - Senior Director, IR*
Thank you very much, Mark, Glen, and Steve. That concludes our prepared presentations. Operator, we'd like to now begin the Q&A.

Operator
Thank you. Our first question comes from the line of Matt Geller from CIBC. Please go ahead.

Matt Geller - *CIBC - Analyst*
Hi, I have two questions for you. First of all, can you talk a little bit about what your thoughts are about potentially partnering Nuvion and Ularitide, when you might think of partnering them, if there has been any interest at this point, and what kind of partnerships you might expect? And second of all, I know that you plan on discussing it in more detail in the springtime, but can you say anything about your plans, are there any trials that might be condensing between now and then for Cardene, Retavase or Busulfex?

Mark McDade - *Protein Design Labs Inc. - CEO*
Good questions, Matt. Thanks. Let me tackle the first one, and then perhaps Steve can tackle the second one. For Nuvion and Ularitide, I can assure you that there has been significant interest in both programs from external potential partners, both bigger biotechs and big pharmaceutical companies. But as we've stated, it's not an objective right now to partner those programs, certainly within our core area of hospital-based approaches where Nuvion we see used in severe refractory ulcerative colitis. That's clearly going to be a hospital-based indication. Ularitide, in the acute setting as we're currently developing it, both in the Europe and the U.S., as again in an acute setting. We think partnering makes sense for those drugs outside of the acute care setting, and that's an area where we may be talking more about the potential in the 2006 timeframe. But near-term, I don't think anyone should expect any announcements in the very near future. Steve, can you maybe address the second one? Again, in that April business update, we do intend to talk more specifically about further investments in our program, but Steve?

Steven Benner - *Protein Design Labs Inc. - Chief Medical Officer*
We have been gearing up for life cycle management activities related to the marketed brands. Those will include a combination of both investigator-initiated studies, as well as studies where PDL will be doing development work to alter the indication, or perhaps broaden it into a different population. For Cardene, we've mentioned that we believe there is an opportunity based on prior use to pursue pediatric exclusivity. For Busulfex, we believe that there's a significant amount of literature that could allow us to broaden the label, based on how the agent has been used in the community. And for Retavase, we're in discussions with a number of academic experts to try and determine what trials would be the most helpful for continuing to demonstrate the importance of lytic therapy in the treatment of acute MI.

Matt Geller - *CIBC - Analyst*
Great. Thanks a lot.

Mark McDade - *Protein Design Labs Inc. - CEO*
Thanks, Matt.

Operator
Our next question comes from the line of Elise Wang from Citigroup. Please go ahead.

Elise Wang - *Citigroup - Analyst*
Thank you. I was wondering if you could, just to help us understand a little bit about the trend lines, what the historical product sales on a quarterly basis were for the three main ESP products over the last two quarters?

Glen Sato - *Protein Design Labs Inc - CFO*
I can tell you on a quarter-over-quarter basis, it's north of 20%, 22% second to third quarter. From the prior quarter, it's not so easy to get a comparison, because if you recall, Retavase actually did not belong to ESP, so there's not really a good comp there overall for all of them.

Mark McDade - *Protein Design Labs Inc. - CEO*
If I can add to that, thanks, Glen, Elise, if you look at what we have stated previously in our various slides, the three products of Cardene and Retavase and IV Busulfex on a full-year basis 2004 did roughly 110 million across the three products. And our new guidance as we've updated it today, has a range of between 108, 113 million just for the nine months and, I think, seven days that we have owned those three drugs. So we think that also points to a trend line of growth for the three drugs combined. The other reason why you can't really look historically prior in the first quarter or previous quarters, for example, is as Glen mentioned just earlier on the call, we did experience when we came in, a fair amount of inventory in the channel, and we've been working through to reduce that as demand grows at the same time.

Elise Wang - *Citigroup - Analyst*
Okay, and also, just, I wanted to check in on this. Is there — in regards to the royalty payments that you receive from Genentech, if I recall, based under the revised agreement with them from a few years ago, there are certain thresholds in which with the product sales and the aggregate reaching those thresholds, your royalty rate would come down a bit. Can you tell me, has that yet happened?

Glen Sato - *Protein Design Labs Inc - CFO*
You know, Elise, I guess the way I would describe it is we don't really break that out specifically. I think we're very pleased by the run rate for the products at this point, and I probably will note for you, it's worth understanding that the U.S. is differentiated from the rest of the world in how that tiering actually applies, so when it happens, you will actually see the impact, I think, be not so dramatic.

Elise Wang - *Citigroup - Analyst*
Okay. And then just one last question. In terms of run rate on expenses, aside from some of the specific one-timers, if you will, and certain of the line items, should we expect to look at the run rate for operating expenses to be a pretty good way of how it should be on an annualized rate, with it growing at some pace in the future periods?

Mark McDade - *Protein Design Labs Inc. - CEO*
You know, obviously, Elise, you'll get more guidance for 2006 on that basis, but I would say certainly this quarter is more representative of fully-integrated ESP as we've brought all of the programs on-line, and as we can say that Retavase has been transferred to us, and the initiation of the related through sales and marketing initiatives, that this quarter's probably more representative than in the past.

Elise Wang - *Citigroup - Analyst*
Okay. And I'm sorry, just one last question. In regards to, now that you are heading into profitability, where that will be more consistent, should we expect to look at your bottom line numbers based on an as-converted basis, given the two outstanding converts?

Glen Sato - *Protein Design Labs Inc. - CFO*
Yes, again, on an as-converted basis, you're right, Elise. We had said last quarter about $130 million on a profit basis for the full year, if you wanted to use the diluted number, it's about 128 is the right number to use in the denominator for profitability, but yes, that would be how to think about it, assuming we would be profitable. Again, that's on a non-GAAP basis.

Mark McDade - *Protein Design Labs Inc - CEO*
Number of shares, not dollars.

Glen Sato - *Protein Design Labs Inc. - CFO*
Right.

Elise Wang - *Citigroup - Analyst*
Okay, thank you.

Operator
Our next question comes from the line of Joel Sendek from Lazard Capital Markets. Please go ahead, sir.

Joel Sendek - *Lazard Capital Markets - Analyst*
Thanks a lot. I actually — good timing here. I have follow-ups on both — or two of Elise's questions, if you could help me out. The first, with regard to the question about the threshold for the Genentech royalties, is it likely that that threshold might be hit either in the U.S. or ex-U.S. this year?

Mark McDade - *Protein Design Labs Inc. - CEO*
We'd prefer not to comment on when the threshold might be hit.

Joel Sendek - *Lazard Capital Markets - Analyst*
Okay. The next is having to do with expenses. Specifically on the SG&A line, you mentioned that this quarter is more representative of what it might likely be, but if — I just quickly ran the numbers for your guidance for SG&A expense for the full year, and specifically, if you look at it on a percentage of revenue basis, it goes down from about 35% this quarter to about 30% next quarter. So I'm a little bit confused. How can this quarter be representative when you're kind of guiding that it's going to go down, at least on a percentage of sales basis next quarter?

Mark McDade - *Protein Design Labs Inc. - CEO*
Well, I think you're going to have some startup costs in particular in a given quarter, Joel, but I think you will overall see the run rate be slightly higher, because I think there are a number of initiatives going on here as we actually get Retavase in hand in particular, and as we look at through building the hospital presence, there are a fair number of promotional efforts that are on the table now with respect to the products now that we feel as though the sales force is up and running and we have, you know, I think a pretty comfortable tactical marketing plan that we want to implement.

Joel Sendek - *Lazard Capital Markets - Analyst*
Thanks.

Operator
Our next question comes from the line of Gil Aharon from Infinium Capital. Please go ahead.

Gil Aharon - *Infinium Capital - Analyst*
Thank you for taking my questions. Two questions, if I may. The first one is, if you could actually disclose some additional details with respect to today's announcement on your deal with Roche on the development of the Zenapax in combination with [Selsem], if you can give us some more details on timing, visibility, and when will the deal close? And secondly, with respect to the expense line as well, to be within your guidance, I believe that some of the R&D expenses and SG&A would have to decline somewhat going into Q4. I guess whether, I'm trying to confirm that this observation.

Steven Benner - *Protein Design Labs Inc. - Chief Medical Officer*
So—

Mark McDade - *Protein Design Labs Inc. - CEO*
You can answer the latter.

Steven Benner - *Protein Design Labs Inc. - Chief Medical Officer*
Why don't you start with the first?

Mark McDade - *Protein Design Labs Inc. - CEO*
Gil, in terms of the Roche deal, we did sign it; it is effectively closed, because there are no other closing conditions, hence the announcement. We have not yet disclosed, as Steve mentioned earlier, our development plans, because the teams are working together as quickly as possible, and we'll be talking more about approximate timelines, probably as soon as the JPMorgan conference coming up in January. But I don't think sooner than 2006 timeframe. So you just have to stay tuned. Steve might be able to comment a little bit to shed some light on what our thoughts are developmentally, however.

Steven Benner - *Protein Design Labs Inc. - Chief Medical Officer*
Yes, as we said, we believe that there was a tremendous opportunity to move Daclizumab from the acute induction setting into the more prolonged treatment setting. And that's what we're working on with our colleagues at Roche in terms of the development program that would allow us to take advantage of the fact that we'll now have a liquid formulation that's appropriate for subcutaneous use, the same formulation that we've been developing with Roche for the treatment of asthma. So we believe that that would be the appropriate way to take Daclizumab forward into the chronic maintenance setting.

Glen Sato - *Protein Design Labs Inc. - CFO*
Gil, to answer your second question, I think it's worth noting, we tried to highlight it on the call, that the approximately $49 million non-GAAP R&D expense line this quarter contained $7.3 million of one-time, if you will, fees and milestone payments. And so you know, we're really talking about a run rate that's lower than that, and obviously, if you kind of look at the running range there, that that's probably pretty representative of what you would see for the

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quarter. I think if you look at the SG&A line, we would be relatively flat to stay within the range consistent with our guidance, again, on a non-GAAP basis.

Gil Aharon - *Infinium Capital - Analyst*
Thanks, but going back again for the development of Daclizumab, if I may. Just to get a sense, because there was some prior — there were some prior trials run by Roche, and are we looking at a more advanced trial, a Phase IIb, a Phase III or you can't disclose any of these thoughts at this time?

Steven Benner - *Protein Design Labs Inc. - Chief Medical Officer*
I think that what we would be working towards is probably a Phase II trial, because we'll be shifting from the Roche manufactured material that's been used in the past, to a chronic subcutaneous administration. Roche has conducted clinical trials in the post marketing setting, that have used IV Zenapax, for doses up to six months, and have shown quite promising results. We'll be trying to build on those fairly rapidly, but I think we'll have to wait until a future discussion to be able to give you a firm timeline.

Gil Aharon - *Infinium Capital - Analyst*
Great, I appreciate that. Thank you.

Operator
Our next question comes from the line of Jason [Beck] with Prudential Equity. Please go ahead.

Jason Zhang - *Prudential Equity - Analyst*

Thanks for taking my question. I wanted to understand your guidance a little better, particularly for the three branded products you are promoting, Cardene, Retavase, and Busulfex. And so your guidance for the three products for this year is 108 to 113 million, and on an annualized basis, that would be close to $150 million for 2005. Would that be the base for us to use if we wanted to achieve 25% year-over-year growth for 2006 estimate?

Glen Sato - *Protein Design Labs Inc - CFO*
No. I think you should use what we reported so that you can actually trace it against what PDL has reported as the annual sale, net sale.

Jason Zhang - *Prudential Equity - Analyst*
Because you don't record any — while you record 300 — you know, 948,000 for the first quarter, so, I really don't know what would be the best. You know, you say 120 million for the year in 2005, but that's only for three quarters actual sales. So how do you really explain the 25% year-over-year growth? You know, full year 2006 versus 3/4 in 2005?

Glen Sato - *Protein Design Labs Inc - CFO*
We would go ahead and report that 25 compound annual growth rate on the basis of what you would see reported by us as PDL net sales. So even though it's nine months and seven days, if you will, for 2005, you would be able to comp it against that on an annual basis because that's all that will be reported for those sales in 2005.

Jason Zhang - *Prudential Equity - Analyst*
I still don't understand, because you know, I just want to make it clear. What would be basis for 2005? If you say okay, the three quarters estimate is 113, and then you have to have an annualized basis for 2005 to figure out what is going to be in 2006. And if I annualize that, that would be 150 million for this year. Are you saying this is too high or too low?

Glen Sato - *Protein Design Labs Inc - CFO*
We are saying that the 25% compound annual growth rate for the first year begins off of the base that is in the range of 108 to 113 million.

Jason Zhang - *Prudential Equity - Analyst*
You're still not helping me. I mean, the 108 and 113 are for three quarters — what is the annualized base?

Glen Sato - *Protein Design Labs Inc. - CFO*
I'm really trying to give the investors the opportunity to be able to compare on the growth rate what we've actually reported as sales, as opposed to speculating what should have been the first quarter number, or providing you with a number that's not consistent with our financial statements, and that's the reason why we've chosen this. That's also the reason why we've also gone out for more than one year to basically say that we continue to invest and grow these products, and our expectations are that even off of a base of 3/4 in the first year, that we would, in fact, continue to see annual growth beyond the first year.

Jason Zhang - *Prudential Equity - Analyst*
Okay, thanks.

Operator
Our next question comes from the line of Tom McGahren from Merrill Lynch. Please go ahead.

Tom McGahren - *Merrill Lynch - Analyst*
Hey, thanks. My question to the follow-up on the Zenapax announcement this morning. I'm just curious about the thinking for PDL deciding not to exercise its option to promote Zenapax, given your sales force, hospital sales force, and sort of the goal of being a fully innovative company. Maybe you could help me with that.

Mark McDade - *Protein Design Labs Inc. - CEO*
Sure, Tom. Let me tackle that. I think there are two parties involved in the thinking: one is Roche, and the other is PDL. And so it's important to look at both of our perspectives, because we are working, we think, very well together, and are very pleased with the relationship. Roche, on the one hand, basically want to continue to maintain and continue to build momentum as a leader in the transplant therapy area, and basically putting Zenapax out of that equation actually might have caused some backward growth or negative repercussions into the marketplace. So that was a concern that we felt we could address as we looked at PDL's needs then. They changed. When we made the original transaction back in 2003, we had targeted Zenapax as our first drug in the commercial environment in North America by 2007, under that agreement. Today it's 2005, and we're already marketing three very fine proprietary products with good growth prospects in and of themselves, and so we actually looked then at Zenapax as in the near-term, since our partner wanted to maintain full and exclusive focus on it, as something that we did not have to undertake in order to build a commercial franchise. And the expense associated with that might also be incrementally deleterious to some of our other efforts. So those two different viewpoints combine to a decision where we also were saved the $20 million exercise fee, and that, together with an up-front, we thought represented pretty considerable value to PDL for maintaining the exclusive rights at Roche for Zenapax. In the meantime, then, we will work very hard with our partner, Roche, on the maintenance opportunity, and build a future commercial plan of attack around that opportunity.

Tom McGahren - *Merrill Lynch - Analyst*
Do you think the up-front milestone and the — or the up-front payment and the milestones together would make you hold financially, compared to as if you actually were actually promoting it yourself?

Mark McDade - *Protein Design Labs Inc. - CEO*
Yes, and particularly when you factor in some of the milestones that are likely to be paid over the next several years as a consequence of the program going forward. We think we're definitely in the black on that approach, and that's not counting any of the shared expenses for the investment in development nor any profit share.

Tom McGahren - *Merrill Lynch - Analyst*
Okay, thanks.

Operator

Our next question comes from the line of Jennifer Chao from Deutsche Bank. Please go ahead.

Jennifer Chao - *Deutsche Bank - Analyst*
Great, thanks for taking the question. Just a couple here, I think. First, how should we think about the activity level of new licensing and humanization partnerships, as well as royalty rates going forward? You know, are those royalty rates trending up? And if you can give us a sense of the magnitude of what to expect in 2006. The second is, if you could just walk us through what the business implications are of a potential invalidation of the Cabilly 2 patents, not only its impact with relationship to your agreement with Genentech, but what does that mean for your business and other potential partners?

Mark McDade - *Protein Design Labs Inc. - CEO*
Jen, this is Mark. Let me try to tackle both of those. On the second one first, we really don't comment on the implications of the Cabilly ongoing discussions. We have not seen any impact on our current discussions in the humanization business, however. So that's how I can address that Cabilly question. On the first one, we've continued to achieve partnerships involving queen licenses to the tune of what we've advertised, which is one or two per year, and we expect to see that on a going forward basis. Some of our later deals, as we've noted, have had slightly increased royalty rates over some of our earlier deals. So the earlier deals range at the lower end of the 3% spectrum. The current deals range in the 3.5 to 3.75% range. And we continue to stick by that guidance on deals going forward. I do expect that you can expect a handful of new announcements next year on a going forward basis. In terms of bigger partnerships, we achieved our goals earlier this year. We have not stated any additional partnering

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objectives for 2006 on the bigger programs. So hopefully, that answers your first question.

Jennifer Chao - *Deutsche Bank - Analyst*
Okay. Yes, that's definitely helpful. Just also, just had one follow-up on your SG&A guidance. I believe you are guiding now 78 to $80 million on the year. I just want to understand, that just implies here that in Q4 you are going to increase your spend significantly. Can you give us a sense of, is there a change in the structure, where that money is going?

Glen Sato - *Protein Design Labs Inc - CFO*
Jen, just a clarification. You're talking about Q4 versus Q3 or you're talking about overall —

Jennifer Chao - *Deutsche Bank - Analyst*
Overall on the year. Is your SG&A trending up here for Q4?

Glen Sato - *Protein Design Labs Inc - CFO*
I think it will be relatively flat if you look at the range and you take the 9-month year-to-date on a non-GAAP basis. We're relatively flat to the third quarter. Part of that is function of the fact that we now have fully built out our sales force as Mark indicated. You know, we've hit the sales force target that we had and we're going to invest in them, but that's a full run right now on a going-forward basis for the rest of the year.

Jennifer Chao - *Deutsche Bank - Analyst*
Mm hmm, mm hmm. Okay, so just to tease you guys a little bit. I mean, how important is profitability for you on the year end?

Mark McDade - *Protein Design Labs Inc. - CEO*
We haven't guided to profitability on a 2005 basis. So we've only talked about non-GAAP positive earnings for the fourth quarter and on a full-year basis in 2006, Jen.

Jennifer Chao - *Deutsche Bank - Analyst*
Okay. Okay, great, thank you.

Mark McDade - *Protein Design Labs Inc. - CEO*
Okay.

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

Jim Goff - *Protein Design Labs Inc. - Senior Director, IR*
Thanks very much, operator. Before we close, I thought it would be helpful to just remind you of the up-coming schedule of investor presentations. These include CIBC in New York on November 7; SG Cowen in Barcelona on November 10; the Lazard conference in late November on the 28th; and also the First Albany conference coming up on December 7. I look forward to seeing many of you at these events and invite you to contact us for further details about any of these programs. Thank you very much, everyone and have a great afternoon.

Operator
Ladies and gentlemen, that does conclude the conference call for today.