UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

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

Date of report (date of earliest event reported):
February 27, 2006

PDL BIOPHARMA, 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):

☐ 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))

Item 2.02. Results of Operations and Financial Condition

On February 27, 2006, PDL BioPharma, Inc. (the "Company") issued a press release (the "Press Release") announcing the Company's financial results for the fourth quarter and fiscal year ended December 31, 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 and other charges. These non-GAAP financial measures are based upon earnings before interest income, interest expense, income taxes, depreciation and amortization (EBITDA), further adjusted to exclude certain non-cash and other charges, including acquired in-process research and development, asset impairment charges and stock-based compensation. 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.

Exhibit No.	Description
99.1	Press Release, dated February 27, 2006, regarding the fourth quarter and fiscal year 2005 financial results of PDL BioPharma, Inc.
99.2	Transcript of earnings call, held on February 27, 2006, regarding the fourth quarter and fiscal year 2005 financial results of PDL BioPharma, 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 3, 2006

PDL BIOPHARMA, INC.

By: /s/ Mark McDade

Mark McDade
Chief Executive Officer

Exhibit 99.1

news release

For Immediate Release

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PDL BIOPHARMA ANNOUNCES FOURTH QUARTER AND FULL YEAR 2005 FINANCIAL RESULTS

— Positive non-GAAP earnings and operating cash flow for fourth quarter and full year —

— Company provides 2006 financial guidance —

FREMONT, Calif., February 27, 2006 – PDL BioPharma, Inc. (PDL, Nasdaq: PDLI) today reported financial results for the fourth quarter and full year ended December 31, 2005.

"Our product and operating revenue increases, during both the fourth quarter and full year, reflect a growing commercial presence in the acute-care hospital market with three proprietary marketed products in Cardene® IV, *Retavase*® and IV *Busulfex*®," said Mark McDade, Chief Executive Officer, PDL. "In addition, royalty revenues from our partners' successful breakthrough antibody products continued to grow, and our new alliances with both Biogen Idec and Roche are bringing important expertise and resources to further propel our clinical-stage pipeline. This overall performance led to positive cash flow from operations for the fourth quarter and the year as well as profitability on a non-GAAP basis. We currently expect to sustain positive non-GAAP earnings for the full year 2006, while advancing our growing pipeline and pushing ahead toward our long-term aims."

PDL's non-GAAP financial results are based on adjusted EBITDA, and the details of the calculation of these non-GAAP financial measures and reconciliation to GAAP financial results are included in the attached financial tables. These non-GAAP results are based upon earnings before interest income, interest expense, income taxes, depreciation and amortization (EBITDA), further adjusted to exclude certain non-cash and other charges, including acquired in-process research and development, asset impairment charges and stock-based compensation.

2005 Financial Results:

- PDL reported a GAAP net loss of $23.1 million, or $0.22 per basic and diluted share, in the fourth quarter of 2005 compared with a net loss of $14.6 million, or $0.15 per basic and diluted share, in the fourth quarter of 2004.

- Fourth quarter 2005 non-GAAP net income was $7.5 million, or $0.07 per basic and $0.06 per diluted share, compared with a non-GAAP net loss of $11.9 million, or $0.12 per basic and diluted share, in the fourth quarter of 2004.
- For the full year 2005, the GAAP net loss was $149.8 million, or $1.45 per basic and diluted share, compared to $53.2 million, or $0.56 per basic and diluted share in 2004.
- PDL reported non-GAAP net income for full year 2005 of $16.2 million, or $0.16 per basic and $0.15 per diluted share, compared to a non-GAAP net loss of $42.1 million, or $0.44 per basic and diluted share in 2004.
- Cash, cash equivalents, marketable securities and restricted investments totaled approximately $333.9 million as of December 31, 2005, compared to $397.1 million as of December 31, 2004.

Total Operating Revenues:

- Total operating revenues for the 2005 fourth quarter were $83.7 million compared to $22.8 million in the same period of 2004, an increase of 266 percent.
  - PDL achieved net product sales of $39.0 million in the fourth quarter of 2005. Net sales of *Cardene*® IV, *Retavase*® and IV *Busulfex*® for the quarter totaled approximately $36.7 million, while net sales of the four off-patent branded products were approximately $2.3 million. PDL did not report sales from marketed products in 2004.
  - Royalty revenues for the fourth quarter of 2005 increased 67 percent to $33.4 million compared with $19.9 million in the year-ago quarter. 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 during the fourth quarter of 2005 increased to $11.3 million from $2.9 million in the same period of 2004, primarily as a result of revenue recognized under the new Biogen Idec collaboration, including $1.4 million of revenue recognized from amortization of upfront or milestone payments received in prior periods.
- Full-year 2005 revenues increased to $276.9 million from $96.0 million in 2004, an increase of 188 percent. PDL achieved net product sales of $118.4 million for the full year 2005. Of this, net sales of *Cardene* IV, *Retavase* and IV *Busulfex* for the year totaled $109.1 million, and net sales of four off-patent branded products were $9.3 million. Net product sales reflected approximately nine months of product sales in 2005 following the acquisition of ESP Pharma, Inc. effective March 23, 2005. Full year 2005 royalty revenues rose to $130.1 million from $83.8 million in 2004. License and other revenues increased to $28.4 million in 2005, compared with $12.2 million for the full 12 months of 2004.

Costs and Expenses:

- Total costs and expenses were $107.8 million in the fourth quarter of 2005, compared with $38.8 million in the fourth quarter of 2004, reflecting the integration of ESP Pharma and *Retavase*, the initiation of new marketing efforts and expanded clinical development activities. On a non-GAAP basis, total costs and expenses in the fourth quarter of 2005 were $76.0 million compared to $34.7 million in the fourth quarter of 2004.
    - The cost of product sales was $16.8 million in the fourth quarter of 2005 compared with no such costs in the fourth quarter of 2004, when PDL did not yet have marketed products. The non-GAAP cost of product sales was $6.2 million in the 2005 fourth quarter, with the difference due to the exclusion of amortization of certain acquisition-related costs.
    - Research and development expenses increased to $47.0 million in the fourth quarter of 2005, compared with $30.2 million in the year-ago period. The increase reflected expanded clinical trial efforts for *Nuvion*®, ularitide and daclizumab, manufacturing-related costs and additional personnel in these areas.
    - Selling, general and administrative expenses increased to $28.0 million during the fourth quarter of 2005, compared with $8.6 million in the fourth quarter of 2004, primarily due to selling expenses associated with PDL's growing sales team as well as the initiation of new promotional efforts late in the third quarter of 2005.
    - Total costs and expenses in the 2005 fourth quarter included asset impairment charges of $16.0 million, primarily related to PDL's option to re-acquire from Roche rights to *Zenapax* for prevention of acute renal transplant rejection, which it will not exercise under an expanded collaboration announced in November 2005.
- Total costs and expenses were $425.3 million for the full year 2005, compared with $154.4 million in 2004. Non-GAAP total costs and expenses were $260.7 million in 2005 compared to $138.6 million for the full 12 months of 2004.
    - For the full year 2005, the cost of product sales was $60.3 million compared with no such costs in 2004, when PDL did not yet have marketed products. The non-GAAP cost of product sales was $24.8 million for the full year 2005, with the difference due to amortization of certain acquisition-related costs.
    - Research and development expenses increased to $172.0 million in 2005, compared with $122.6 million in the full year 2004. The increase reflected expanded clinical development activities for the company's mid- and late-stage products, manufacturing-related costs and additional personnel in these areas.
    - Selling, general and administrative expenses increased to $82.3 million for the full year 2005, compared with $31.8 million in 2004, primarily due to sales expenses associated with the marketing of *Cardene*, *Retavase* and *Busulfex* following the March 2005 acquisitions of ESP Pharma and *Retavase*.

Note: PDL's non-GAAP financial results are based on adjusted EBITDA. Reconciliations of GAAP results to non-GAAP results for the reported periods are included in the tables accompanying this release. Non-GAAP results for the three- and 12-month periods ended December 31, 2005 and 2004 exclude certain non-cash and other charges. For the full year 2005, these consisted primarily of the following: an acquired in-process research and development charge of $79.4 million related to the ESP Pharma acquisition; asset impairment charges of $15.5 million related to the off-patent branded products and of $15.8 million related to the option to re-acquire rights to manufacture and market *Zenapax* for acute renal transplant rejection; the amortization of intangible assets of $37.6 million associated with the Eos Biotechnology, Inc., ESP Pharma and *Retavase* acquisitions and the re-acquisition from Roche of rights to develop and market *Zenapax* in indications other than transplantation; depreciation expenses for fixed assets of $15.4 million; and stock-based compensation charges of $1.0 million. Our non-GAAP results include upfront license and certain milestone payments that are recognized over time, which totaled $9.2 million for the fiscal year related to the Biogen Idec and Roche collaborations.

2006 Forward-looking Guidance:

The following statements are based on current expectations as of February 27, 2006, 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 anticipates total operating revenues for 2006 in a range of approximately $405 million to $435 million, including $175 million to $185 million in net product revenues and $170 million to $180 million in royalties. Revenue guidance also includes license fees and total collaboration revenues (expense reimbursement and the amortization of upfront fees and milestone payments) of approximately $60 million to $70 million.
- On a non-GAAP basis, PDL anticipates total costs and expenses in 2006 as follows: cost of product sales to be approximately $40 million; research and development expenses in a range of approximately $230 million to $240 million, reflecting significant planned investments for clinical development of later stage and partnered products, as well as select development activities to support currently marketed products; and selling, general and administrative expenses in a range of approximately $90 million to $100 million.
- For the full year 2006, PDL anticipates adjusted EBITDA in a range of approximately $44 million to $54 million, or on a diluted per share basis, in the range of $0.38 to $0.47. This forward-looking guidance excludes certain non-cash charges based on current estimates for the full year 2006, including the impact of stock option compensation expense in a range of approximately $32 million to $38 million, and the amortization of certain expenses of approximately $44 million related to the acquisitions of ESP Pharma and *Retavase*, and the re-acquisition from Roche of rights to develop and market *Zenapax* in indications other than transplantation. Other items that could affect the reconciliation cannot be estimated at this time because they depend upon future events.

- For the full year 2006, PDL anticipates ending the year with more than $370 million in cash, cash equivalents, marketable securities and restricted investments. This figure includes the repayment of a $30 million note receivable, plus interest, from Exelixis, Inc., expected in May 2006.

* * * * *

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; 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 in part 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. 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 revenues and expenses would be affected by new collaborations, material patent licensing arrangements or other strategic transactions.

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 BioPharma

PDL BioPharma, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life threatening illnesses. The company currently markets and sells a portfolio of leading products in the acute-care hospital setting in the United States and Canada and generates royalties through licensing agreements with top-tier biotechnology and pharmaceutical companies based on its pioneering humanized antibody technology. Currently, PDL BioPharma's diverse late-stage product pipeline includes six

investigational compounds in Phase 2 or Phase 3 clinical development for hepatorenal syndrome, inflammation and autoimmune diseases, cardiovascular disorders and cancer. For more information, please see our website at www.pdl.com.

Financial tables attached

PDL BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

(In thousands, except per share data)	Three months ended December 31, 2005	Three months ended December 31, 2004	Twelve months ended December 31, 2005	Twelve months ended December 31, 2004
Revenues:				
Product sales, net	$ 39,012	$ —	$ 118,449	$ —
Royalties	33,373	19,935	130,068	83,807
License and other	11,268	2,894	28,395	12,217
Total revenues	83,653	22,829	276,912	96,024
Costs and expenses:				
Cost of product sales	16,776	—	60,257	—
Research and development	46,959	30,199	172,039	122,563
Selling, general and administrative	28,028	8,624	82,295	31,806
Asset impairment charges	16,044	—	31,269	—
Acquired in-process research and development	—	—	79,417	—
Total costs and expenses	107,807	38,823	425,277	154,369
Operating loss	(24,154)	(15,994)	(148,365)	(58,345)
Interest and other income, net	2,781	2,523	9,616	10,212
Interest expense	(2,655)	(1,099)	(10,177)	(5,028)
Loss before income taxes	(24,028)	(14,570)	(148,926)	(53,161)
Income taxes expense (benefit)	(899)	12	868	80
Net loss	$ (23,129)	$ (14,582)	$ (149,794)	$ (53,241)
Basic and diluted net loss per share	$ (0.22)	$ (0.15)	$ (1.45)	$ (0.56)
Shares used in computation of basic and diluted net loss per share	107,512	95,613	103,311	94,982

PDL BIOPHARMA, INC.
NON-GAAP CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

We use certain non-GAAP financial measures in evaluating our operating performance. These non-GAAP financial results are based upon earnings before interest income, interest expense, income taxes, depreciation and amortization (EBITDA), further adjusted to exclude certain non-cash and other charges, including acquired in-process research and development, asset impairment charges and stock-based compensation. We believe that these non-GAAP financial 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.

(In thousands, except per share data)	Three months ended December 31,					
	2005			2004		
	GAAP	Adjustments	Non-GAAP	GAAP	Adjustments	Non-GAAP
Revenues:						
Product sales, net	$ 39,012		$ 39,012	$ —		$ —
Royalties	33,373		33,373	19,935		19,935
License and other	11,268		11,268	2,894		2,894
Total revenues	83,653		83,653	22,829		22,829
Costs and expenses:						
Cost of product sales	16,776	$ (10,565)[1]	6,211			
Research and development	46,959	(4,371)[2]	42,588	30,199	$ (3,563)[2]	26,636
Selling, general and administrative	28,028	(820)[3]	27,208	8,624	(526)[3]	8,098
Asset impairment charges	16,044	(16,044)[4]	—	—		—
Total costs and expenses	107,807	(31,800)	76,007	38,823	(4,089)	34,734
Operating income (loss)	(24,154)	31,800	7,646	(15,994)	4,089	(11,905)
Interest and other income, net	2,781	(2,889)[5]	(108)	2,523	(2,505)[5]	18
Interest expense	(2,655)	2,655	—	(1,099)	1,099	—
Income (loss) before income taxes	(24,028)	31,566	7,538	(14,570)	2,683	(11,887)
Income taxes expense (benefit)	(899)	899	—	12	(12)	—
Net income (loss)	$ (23,129)	$ 30,667	$ 7,538	$ (14,582)	$ 2,695	$ (11,887)
Net income (loss) per basic share	$ (0.22)		$ 0.07	$ (0.15)		$ (0.12)
Net income (loss) per diluted share	$ (0.22)		$ 0.06	$ (0.15)		$ (0.12)
Shares used in computation of net income (loss) per basic share	107,512		107,512	95,613		95,613
Shares used in computation of net income (loss) per diluted share	107,512		116,514	95,613		95,613

(1) Amortization of intangible assets for our marketed products in Q4'05.

(2) Depreciation expenses for our fixed assets ($3.8M in Q4'05, $2.9M in Q4'04), and amortization of intangible assets associated with the Eos Biotechnology, Inc. acquisition and the re-acquisition from Roche of rights to Zenapax ($0.6M in Q4'05, $0.6M in Q4'04).

(3) Depreciation expenses for our fixed assets ($0.4M in Q4'05, $0.2M in Q4'04), and stock-based compensation ($0.4M in Q4'05, $0.3M in Q4'04).

(4) Asset impairment charges for off-patent brands of $0.2M and write-off of option to re-acquire rights to manufacture and market *Zenapx* for acute renal transplant rejection of $15.8M in Q4'05.

(5) Interest income.

PDL BIOPHARMA, INC.
NON-GAAP CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

We use certain non-GAAP financial measures in evaluating our operating performance. These non-GAAP financial results are based upon earnings before interest income, interest expense, income taxes, depreciation and amortization (EBITDA), further adjusted to exclude certain non-cash and other charges, including acquired in-process research and development, asset impairment charges and stock-based compensation. We believe that these non-GAAP financial 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.

(In thousands, except per share data)	Years ended December 31,					
	2005			2004		
	GAAP	Adjustments	Non-GAAP	GAAP	Adjustments	Non-GAAP
Revenues:						
Product sales, net	$ 118,449		$ 118,449	$ —		$ —
Royalties	130,068		130,068	83,807		83,807
License and other	28,395		28,395	12,217		12,217
Total revenues	276,912		276,912	96,024		96,024
Costs and expenses:						
Cost of product sales	60,257	(35,434)[1]	24,823			
Research and development	172,039	(16,396)[2]	155,643	122,563	(14,280)[2]	108,283
Selling, general and administrative	82,295	(2,094)[3]	80,201	31,806	(1,519)[3]	30,287
Asset impairment charges	31,269	(31,269)[4]	—			
Acquired in-process research and development	79,417	(79,417)	—	—		—
Total costs and expenses	425,277	(164,610)	260,667	154,369	(15,799)	138,570
Operating income (loss)	(148,365)	164,610	16,245	(58,345)	15,799	(42,546)
Interest and other income, net	9,616	(9,664)[5]	(48)	10,212	(9,739)[5]	473
Interest expense	(10,177)	10,177	—	(5,028)	5,028	—
Income (loss) before income taxes	(148,926)	165,123	16,197	(53,161)	11,088	(42,073)
Income taxes expense	868	(868)	—	80	(80)	—
Net income (loss)	$(149,794)	$ 165,991	$ 16,197	$ (53,241)	$ 11,168	$ (42,073)
Net income (loss) per basic share	$ (1.45)		$ 0.16	$ (0.56)		$ (0.44)
Net income (loss) per diluted share	$ (1.45)		$ 0.15	$ (0.56)		$ (0.44)
Shares used in computation of net income (loss) per basic share	103,311		103,311	94,982		94,982
Shares used in computation of net income (loss) per diluted share	103,311		109,222	94,982		94,982

(1) Amortization of intangible assets for our marketed products in 2005.

(2) Depreciation expenses for our fixed assets ($14.2M in 2005, $11.0M in 2004), amortization of intangible assets associated with the Eos Biotechnology, Inc. acquisition and the re-acquisition from Roche of rights to Zenapax ($2.1M in 2005, $2.5M in 2004), restructuring charges (none in 2005, $0.3M in 2004), and stock-based compensation ($0.2M in 2005, $0.6M in 2004).

(3) Depreciation expenses for our fixed assets ($1.2M in 2005, $0.8M in 2004), and stock-based compensation ($0.8M in 2005, $0.6M in 2004).

(4) Asset impairment charges for off-patent brands of $15.5M and write-off of option to re-acquire rights to manufacture and market *Zenapx* for acute renal transplant rejection of $15.8M in 2005.

(5) Interest income.

CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

(In thousands)	December 31, 2005	December 31, 2004*
		(unaudited)
Cash, cash equivalents, marketable securities and restricted investments	$ 333,922	$ 397,080
Total assets	1,170,262	713,732
Total stockholders' equity	531,144	412,510

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

CONSOLIDATED STATEMENT OF CASH FLOW DATA
(Unaudited)

	Three months ended December 31, 2005	Year ended December 31, 2005
Net loss	$ (23,129)	$ (149,794)
Adjustments to reconcile net loss to net cash provided by operating activities	22,858	167,489
Changes in assets and liabilities	2,368	13,620
Net cash provided by operating activities	$ 2,097	$ 31,315

Exhibit 99.2

PDL BioPharma Q4 and Year-End 2005
Earnings Conference Call
Event Date/Time: Feb. 27. 2006 / 4:30PM ET

CORPORATE PARTICIPANTS

Ami Knoefler
PDL BioPharma - Senior Director, Investor and Corporate Relations
Mark McDade
PDL BioPharma - CEO
Steven Benner
PDL BioPharma - Chief Medical Officer

CONFERENCE CALL PARTICIPANTS

Joel Sendek
Lazard Capital Markets - Analyst
Bret Holley
CIBC World Markets - Analyst
Jason Zhang
Prudential Equity Group - Analyst
Phil Nadeau
SG Cowen - Analyst
Eric Hoffman
JP Morgan - Analyst
Tom McGahren
Merrill Lynch - Analyst
Katherine Xu
Pacific Growth Equities - Analyst
Craig Parker
Lehman Brothers - Analyst

Operator

Welcome to the PDL BioPharma Q4 and year end earnings 2005 conference call.
[OPERATOR INSTRUCTIONS]. As a reminder, this conference is being recorded Monday, February 27, 2006. I would now like to turn the conference over to Ami Knoefler, Senior Director, Corporate and Investor Relations. Good afternoon, ma'am.

Ami Knoefler - *PDL BioPharma - Senior Director, Investor and Corporate Relations*

Good afternoon, everyone and thank you for joining us today. With me are Mark McDade, Chief Executive Officer, and Dr. Steven Benner, our Chief Medical Officer, and for Q&A, we will be joined by George Jue, PDL's Vice President Finance, and Chief Accounting Officer. During today's call, we will begin by previewing our fourth quarter and full-year 2005 financial results. Steve will then provide an overview of recent clinical highlights and Mark will discuss our 2006 financial guidance and provide a quick recap of our 5-year plan, Vision 2010. Let me remind you that the information we 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 will now turn the call over to Mark McDade, PDL BioPharma's Chief Executive Officer.

Mark McDade - *PDL BioPharma - CEO*

Thanks, Ami, and thanks to all of you for joining us today. I'm very pleased to welcome you to PDL BioPharma's first official earnings call. In conversations with numerous investors and analysts in 2006, many of you have commented on the degree of difference at PDL. We have changed, changed so much that we changed our name, adding BioPharma to better reflect our status as a commercially capable biopharmaceutical company while retaining our heritage with PDL as a leader in the antibody space. The new PDL is a dynamic enterprise, staffed by just over a thousand employees with three proprietary marketed products, a focus on the acute care hospital marketplace, and an exciting pipeline of six novel programs, four antibodies and two peptides that address significant and unmet medical needs.

2005 was a remarkable and productive year for all of us involved with PDL. We achieved our commercialization goal two years ahead of schedule. We bought a company and another product, we announced positive Phase II data for ularitide and pushed forward toward a potential three products in pivotal studies by the end of this year, 2006. We entered two new alliances, one with Biogen IDEC and the second with Roche, and very significant to US investors, we achieved our financial goal of achieving positive cash flow, not just in the fourth quarter, but for the full year.

Clearly, some of the progress we've made is reflected in the numbers just reported today. Change starts at the top line with revenue growth of 266%, and 188% for the quarter, and the year respectively. Obviously, those growth rates reflect the addition of product sales revenue from our acquisitions of ESP Pharma and Retavase, and they underscore our focus on commercialization. In the months following the acquisitions, we've successfully integrated and retained our new sales force, while expanding it to a total of 105 talented representatives that support our three key brands: Cardene I.V., Retavase, and I.V. Busulfex. As evidenced by our overall results in 2005, the sales force have made significant inroads in penetrating roughly double the number of hospitals called on in Q1 of '05 and increasing net product sales. I believe this achievement is a promising sign of the new PDL at work. Central to advancing our business is building an even deeper and more exciting biotech pipeline, funded in part by strong global partners who are committed to shared development and commercialization of novel biologic products.

Both our new partnership with Biogen IDEC and our expanded partnership with Roche, which pertain to our the mid-stage products that address needs in multiple sclerosis, oncology and transplant maintenance reflect this commitment. At the same time, we are more focused than ever on advancing our unpartnered later-stage programs. We are in a position to have three breakthrough molecules in pivotal studies by year end, terlipressin, already in Phase 3, Nuvion, which is underway in a pivotal Phase 2-3 study and Ularitide, which we are targeting for Phase 3 initiation in Europe by the end of this year. We also anticipate initiating a Phase 1 study in late 2006 of a new humanized antibody in the setting of multiple myeloma, delivering on our promise to build our pipeline by starting clinical trials for at least one new antibody product per year.

Steve will shortly provide an update on the status and plans of our clinical programs, but from my perspective, our pipeline has never been more robust, and our 2005 progress has enabled us to kick off 2006 on a track to have our three most advanced products in, entering, or perhaps even completed Phase 3 by the end of this year. These significant achievements reflect our enduring commitment to building a commercial infrastructure while building a deeper clinical pipeline. The fact that we have been able to do this and achieve positive cash flow in the fourth quarter and full year 2005 should be viewed favorably given the monumental challenges associated with growing a sustainable biopharma company. In my view, the achievements of 2005 have been made possible by our growing stream of royalty revenue, that helps us offset the investment of creating commercial infrastructure and building our pipeline. We continue to benefit from the success of our licensees: Genentech, MedImmune, Wyeth and Roche, whose breakthrough antibody-based products are driving double-digit growth in PDL's royalty revenues. With more than $4 billion in licensed product sales worldwide by our licensees during the last four quarters, we

are proud of our licensees' accomplishments and believe we will continue to benefit from a growing royalty stream from these and potentially other future approved products.

Now, let me briefly review our financial results in the fourth quarter and full year 2005, which were characterized by a continued strong revenue growth and achievement of positive cash flow. Total operating revenues increased to $83.7 million in the fourth quarter of 2005 compared to $22.8 million in the fourth quarter of 2004. Total operating revenues increased to $276.9 million for the full year of '05 at the upper end of our guidance from $96 million for the full year 2004, an increase of 188%. This overall increase is due both to the addition of product sales as a result of our ESP Pharma and Retavase acquisitions, and strong royalty revenue growth driven principally by growth of licensed antibodies marketed by Genentech and MedImmune.

PDL recognized net product sales of $39 million in the fourth quarter of 2005 and net product sales of $118.4 million for the full year. Our three key marketed products are Cardene I.V., for the short-term treatment of hypertension when oral therapy is not feasible or desirable, Retavase, used to dissolve coronary blood clots and improve blood flow in heart attack patients, and I.V. Busulfex, a conditioning agent used in connection with bone marrow transplants in chronic myelogenous leukemia. During the fourth quarter, sales of these three products totaled approximately $36.7 million, while sales of the up patent branded products were about $2.3 million. We are very pleased with these results and believe our sales closely track with end user demand.

We have continued our progress, aimed at low wholesaler inventories, which aids our visibility into end user demand. Cardene continues to be placed on more hospital protocols each day as our recently expanded sales force reaches more customers. With Retavase, we did experience a period of roughly one month where we were unable to ship product due to delays related to a label changeover from the original Centocor label, and this obviously impaired our fourth quarter Retavase net sales results. We are, however, encouraged that our efforts to promote Retavase are beginning to have a positive impact as evidenced by recent NDC data, which show that in December 2005 as well as January 2006 we have gained market share in the AMI segment. Our year end performance with net product sales of $118.4 million for roughly nine months of 2005 reflects growth throughout the year, largely driven by Cardene and the efforts of our expanded sales and marketing team, their on-going promotional activities and the penetration across more than 1600 hospitals and major acute care centers in the U.S. With our commercial infrastructure in place, we are launching new promotional initiatives in '06, specifically to support Cardene and Retavase, and are currently evaluating targeted label expansion investments in these products to build longer-term sales. We plan on discussing these initiatives and providing more detailed and disaggregated product sales analysis as part of our forthcoming business update, now targeted for the beginning of May, following the release of our first quarter 2006 results.

Revenue growth also included a 67% increase in royalties, which were $33.4 million during the fourth quarter compared with royalty revenues of $19.9 million in the same quarter last year. PDL's full year 2005 royalty revenues were $130.1 million, which met the high end of our guidance range compared to $83.8 million for 2004. As you know, PDL receives royalties based on worldwide net sales of seven antibody products licensed under our antibody humanization patents. Most notably during 2005, we've seen strong growth from the four licensed Genentech antibody products, Avastin, Herceptin, Xolair and Raptiva.

Remember that we book royalty revenues based on sales in the prior quarter You should also note that a small portion of the royalties, roughly $1.2 million, was paid to PDL for sales of generic declomycin by Glades Pharmaceuticals. Fourth quarter revenues included $11.3 million in license fees, reimbursements and other revenues, a significant increase from the same period in 2004, largely due to payments under the new Biogen Idec and Roche collaborations. There are two important elements of this revenue: The

first is payments for reimbursement of expenses, which are currently recognized as revenue, and which will become increasingly important during 2006 as we increase the scope of our clinical stage programs covered under these two large alliances. The second element is up-front fees and milestones under our collaborations which are amortized over time.

So now let's turn to expenses. Our cost of product sales was $16.8 million in the fourth quarter and $60.3 for the full year 2005. PDL did not report sales in the comparable periods of 2004 prior to the addition of ESP Pharma in March, 2005, and therefore it did not report cost of sales for 2004. Excluding non-cash amortization of product costs associated with the purchases of ESP and Retavase, cost of product sales was $6.2 million in fourth quarter of 2005, and $24.8 million for the full year 2005. Selling, general and administrative expenses increased to $28 million compared to $8.6 million in the fourth quarter of 2004, primarily due to selling and marketing expenses associated with PDL's new sales and strategic marketing teams. For the full year 2005, selling, general, and administrative expenses increased to $82.3 million compared to $31.8 million for the full year 2004, reflecting our rapid integration of the new commercial business infrastructure and increased promotional costs focused on our three new marketed brands.

Research and Development expenses increased to $47 million in the fourth quarter of 2005 compared with $30.2 million in the same three months of 2004. For the full year 2005, Research and Development expenses increased to $172 million compared with $122.6 million for 2004. The increase in Research and Development expenses reflects our continued increase in clinical trial efforts, manufacturing-related efforts, and planned growth in personnel in these areas. More importantly, this increase is due to advancement of several programs into later-stage development and the acquisition earlier in the year of two later-stage programs. In particular, we have initiated or plan to initiate new studies for ularitide and Nuvion and have expanded our daclizumab program in MS and transplant maintenance.

Total cost and expenses were $107.8 million in the fourth quarter of 2005, compared with $38.8 million in the fourth quarter of 2004. This includes $16 million of non-cash impairment charges during the fourth quarter, primarily related to PDL's option to acquire from Roche the rights to Zenapax for prevention of acute kidney transplant rejection. As you know, we will not exercise that right under the new and expanded collaborative arrangement with Roche announced in November of 2005, so the impairment charge was made to reflect the elimination of that right.

Other non-cash expenses in the fourth quarter included amortization of intangible assets of $11.1 million and depreciation expense of $4.3 million. On a non-GAAP basis, total costs and expenses for the full year 2005 were $260.7 million compared with $138.6 million for 2004. Non-GAAP adjustments for the full year 2005 included primarily an acquired in-process Research and Development charge of $79.4 million in the first quarter related to the ESP Pharma acquisition. Asset impairment charges of $31.3 million related to the off-patent branded products and write off of the option to acquire from Roche the rights to Zenapax for prevention of acute kidney transplant rejection, and the amortization of intangible assets of $37.6 million associated with the Eos Biotechnology Inc. and ESP Pharma and Retavase acquisitions as well as the reacquisition of rights to manufacture and market Zenapax in 2003, plus stock-based compensation charges. Reconciliations of GAAP results to non-GAAP results are included in the tables accompanying our quarterly press release, and are available on our website.

We have historically used non-GAAP financial measures in evaluating the Company's operating performance and for budgeting and planning purposes. Our company and its financial objectives have changed significantly since the beginning of 2005. So for 2006, we are introducing a new measure in our financial table starting with today's release. Today and subsequently, we intend to provide GAAP results as well as non-GAAP numbers based upon adjusted EBITDA calculations to provide you with a clearer understanding of our operating results.

Adjusted EBITDA, as reflected in our report under "earnings" is net income before interest income,

interest expense, income taxes, depreciation and amortization, or EBITDA, adjusted to exclude certain non-cash and other charges. These adjustments include amounts related to asset impairment charges acquired in process research and development and stock-based compensation. Therefore, using adjusted EBITDA as a basis, our non-GAAP net income for the fourth quarter of 2005 was $7.5 million or $0.07 per basic and $0.06 per diluted share, compared with a non-GAAP net loss of $11.9 million or $0.12 per basic and diluted share in the 2004, fourth quarter. Going forward, this is a key metric by which we intend to measure our performance and believe it will provide you the greatest visibility of our underlying financial performance.

PDL reported a GAAP net loss of $23.1 million or $0.22 per basic and diluted share in the fourth quarter of 2005 compared with a GAAP net loss of $14.6 million or $0.15 per basic and diluted share in the fourth quarter of 2004. Using adjusted EBITDA as a basis, our non-GAAP net income for the full-year of 2005 was $16.2 million or $0.16 per basic and $0.15 per diluted share compared to a non-GAAP net loss of $42.1 million or $0.44 per basic and diluted share in 2004. In addition, positive cash flow from operations was even higher than our non-GAAP income at approximately $31.3 million for full year 2005. For full year ‘05, the GAAP net loss was $149.8 million or $1.45 per basic and diluted share compared to $53.2 million or $0.56 per basic and diluted share in 2004. Overall, we believe these results for the fourth quarter and full year 2005 mark a tremendous achievement for PDL. We delivered positive cash flow in the fourth quarter of 2005 and feel we are tracking consistent with our aim to start sustainably delivering earnings for full year 2006 and beyond.

At this time, I’d like to turn the call over to Steve Benner, our Chief Medical Officer, to review our clinical programs.

Steven Benner - *PDL BioPharma - Chief Medical Officer*

Thanks, Mark. I’d like to focus on a brief update of three products we believe are closest to market. 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 3 clinical trial is being conducted by our partner, Orphan Therapeutics. Terlipressin is an approved drug in Europe for the treatment of esophageal varices and other complications of advanced liver disease.

Type 1 hepatorenal syndrome is associated with a very high mortality rate, and currently there are no approved medical therapies. We expect the trial to enroll approximately 120 patients, and to be in a position to report the study results for the fourth quarter of 2006. To date well over three-quarters of the patients have been accrued and as the pace of accrual has picked up, it may be possible to complete the trial earlier.

Nuvion or visilizumab, our humanized anti-CD3 antibody, is in development for the treatment of I.V. steroid refractory colitis. Earlier this quarter we’ve begun enrollment in the first pivotal trial, the Phase 2-3 study and believe we are on track pending a positive DSMB review later this year to initiate the second pivotal study by the end of the calendar year. Small open-label pilot studies of Nuvion and Crohn’s disease are on-going. At DDW in May 2006 there will be an oral presentation of the initial findings of one of the Crohn’s disease pilot studies. As we indicated earlier this year, we’ve seen activity with Nuvion in this setting, including patients previously exposed to or unresponsive to imfliximab. We are currently creating a development plan to guide future studies of Nuvion and Crohn’s disease and will plan on discussing this in greater detail during our Fall R&D update in New York.

Ularitide, the naturetic peptide derived from the pro hormone of ANP has shown promise in a Phase 2 trial reported at the European Study of Cardiology last year. We now have an open IND and are in the process of finalizing the study design based on comments from the FDA. We look forward to moving this U.S. trial ahead as soon as possible.

Separately, we are discussing with the European Medicines Agency, the EMEA, the possibility of using data from a single Phase 3 study as the basis for a market authorization application in the European Union using the scientific advice procedure. If these efforts are successful, we believe we're on track with our stated objective of initiating a pivotal trial to support European registration in the second half of this year. We also hope to take full advantage of the potential EU pivotal trial as a component to support the U.S. dossier.

For daclizumab, our anti-IL2 receptor antibody, both single-dose and multiple-dose studies of subcutaneously administered PDL-manufactured daclizumab in healthy volunteers have completed dosing. We are in the process of collecting data from these trials. These studies are a necessary component of switching to the PDL-manufactured antibody that is formulated for subcutaneous administration. In collaboration with our partner, Roche, the next step in the development of daclizumab in asthma is a Phase 2-B dose-range finding study in patients with chronic, persistent asthma.

We hope to begin this study in collaboration with Roche in the second half of 2006. You will recall that we also have an on-going study of daclizumab in patients with relapsing, remitting multiple sclerosis. This trial, initiated by PDL, is now part of our collaboration with Biogen Idec. The initial randomized placebo-controlled study evaluates daclizumab as an add-on to beta-interferon in patients with active, relapsing forms of MS using the Roche manufactured antibody. We will close this trial to further enrollment in March. The final sample size is estimated to be 165 patients, smaller than the initially-predicted 270. The trial will allow us to confirm the activity in a blinded study in a similar patient population as was previously studied at the NIH in open-label trials.

Through our collaboration, a second monotherapy trial will be initiated this year using PDL-manufactured antibody, this development plan will allow us to have data from two randomized trials in MS and is not expected to prolong the time line. The monotherapy trial is a randomized placebo-controlled study evaluating three daclizumab dosing regimens. The study will have an MRI end point and is expected to enroll 264 patients. We are pleased to have the expertise of Biogen Idec in MS to strengthen the development plan for daclizumab in this disease setting. Daclizumab is additionally partnered with Roche for development as a maintenance agent for solid organ transplants. Our future plans for the new transplant maintenance efforts will be discussed in greater detail later this year as we and our partner Roche fully refine and agree on the next steps.

Volociximab, also known as M200 is an anti-angiogenic antibody that binds to alpha 5-Beta 1 integrant, and is under development as a treatment for solid tumors. We continue to anticipate the first public release of data from at least two of the on-going open-label Phase 2 studies in solid tumors around the time of the ASCO meeting in the 2nd quarter of 2006. We are developing volociximab in collaboration with our partner, Biogen Idec.

Overall during 2005, I believe we continued to make great strides in advancing our multiple clinical stage programs, which address a number of important and unmet medical needs. In addition, our collaborations with Roche and Biogen Idec are facilitating broader and more rapid study of three of our Phase 2 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 to discuss 2006 guidance and summarize our new five-year plan, Vision 2010.

Mark McDade - *PDL BioPharma - CEO*

Thank you, Steve. Looking ahead to year end, I am sure you'll agree that the Company has some significant and exciting activities, including the possibility of three of our latest-stage products being in Phase 3 programs by the end of the year. We expect these pipeline advancements and the associated R&D

investment to be coupled with continued top-line growth from our current product portfolio and solid royalty revenue stream, but also expect to be profitable on a non-GAAP basis.

As I mentioned, our non-GAAP numbers are based on the adjusted EBITDA and the reconciliations we have described on this call and in our press release issued earlier today. Specifically, PDL expects that total operating revenues for 2006 will range from approximately $405 million to $435 million, including $175 million to $185 million in product revenues and $170 million to $180 million in royalties. Revenue guidance also includes license fees and total collaboration revenues defined earlier as expense reimbursement and the amortization of up-front fees and milestones of approximately $60 to $70 million.

Many of you have inquired about the scope of anticipated reimbursement fees during 2006 associated with our collaborations with Biogen Idec and Roche. As we see those alliances progress, we expect well over half, or approximately $40 million of these licensing collaboration revenues to be associated with these significant collaborations, enabling us to continue advancing our mid-stage pipeline and maximizing the product opportunities for both alliances across patient populations from daclizumab in asthma, multiple sclerosis and transplant maintenance to M-200 in multiple tumor types and HuZAF in autoimmune diseases such as rheumatoid arthritis.

On a non-GAAP basis, PDL anticipates total cost and expenses in 2006 as follows: Cost of product sales to be approximately $40 million, and we reaffirm our goal to maintain 80% gross margins on our marketed products through 2008 on a non-GAAP basis, or excluding amortization charges. Research and Development expenses in a range of approximately $230 million to $240 million, reflecting significant planned investments for clinical development of later-stage, such as the planned pivotal programs for Ularitide and Nuvion, as well as funding our share of the co-development expense for the partnered programs. These expenses also anticipate select development activities to support and extend the opportunities for our currently marketed products. These expenses exclude depreciation expense, tied largely to our new production facility of approximately $25 million for 2006.

Selling, general, and administrative expenses in a range of approximately $90 to $100 million, reflecting modest growth in our commercial infrastructure and appropriate preparations to support terlipressin as it approaches the market as the first potential treatment for Type I hepatorenal syndrome and the first drug launched by PDL BioPharma. We excluded from our non-GAAP numbers stock compensation expense, which we cannot estimate with certainty at this time, but which we anticipate to be in a range between $32 and $38 million. For the full year 2006, PDL anticipates non-GAAP earnings based upon adjusted EBITDA in the range of approximately $44 million to $54 million. On a per share basis, PDL anticipates non-GAAP earnings of approximately $0.38 to $0.47 per diluted share for the full year 2006.

As we discussed, this forward-looking guidance excludes certain non-cash charges based on current estimates for the full year 2006, including the impact of stock option compensation expense and amortization of certain expenses of approximately $44 million related to the acquisitions of EOS Biotechnology, ESP Pharma and Retavase, and the reacquisition from Roche of rights to develop and market Zenapax in indications other than transplantation.

Note that our non-GAAP results include license fees and milestones that we have received as to which we recognize revenue over time. Our 2006 results will not include any significant revenue from sales of the four off-patent products acquired with ESP Pharma in March, 2005 as we completed the sale of one Declomycin, and expect to conclude the sale of the other three smaller-volume products quite shortly.

Looking beyond 2006, at recent investor conferences in San Francisco and New York, we’ve shared our enthusiasm and our aims for the future in a plan we refer to as Vision 2010. We’ve outlined that if we successfully market our drugs and achieve first or second dollar market share positions, expand

operations commercially in Europe and successfully develop and launch our three most advanced drug candidates over the next five years, then we believe we can reach total operating revenues of roughly $1 billion by the end of 2010, and so long as we continue to steadily shrink our ratio of R&D to revenues, we believe we'll build year after year sustainable non-GAAP earnings by at least 25% between 2006 and 2010.

We're excited about these new aims and more specifically, about the promise of our numerous pipeline opportunities. And we're committing to you that the roughly thousand employees of PDL BioPharma are doing their very best day after day to deliver on our vision for 2010. In closing, I'd like to acknowledge that Dr. Cary Queen has resigned from our Board of Directors, as announced in a filing earlier today. As the founder of PDL and key inventor of our antibody-based technology, Dr. Queen's efforts led to the breakthrough today known as humanized antibodies, leading to significant treatment advances for a variety of serious health conditions. His scientific innovations have been fundamental to building our company, and we are grateful for his years of service and contributions to PDL. Dr. Queen will continue to act as a consultant to the Company so that we can continue to benefit from his knowledge and expertise. All of us at PDL BioPharma are grateful for Cary's many contributions, as a scientist, inventor, co-founder, manager, and director. Thank you, Cary. I'd like to close by expressing my thanks to all of our partners, collaborators, advisors, employees, directors, and shareholders for helping us continue to build an exciting new kind of drug company, PDL BioPharma. Now let me turn the call back over to Ami.

Ami Knoefler - *PDL BioPharma - Senior Director, Investor and Corporate Relations*

Thank you, Mark and Steve. That concludes our prepared remarks, Operator, please begin the Q&A.

Question and Answer Session

Operator

Thank you. [OPERATOR INSTRUCTIONS]. One moment, please, for our first question. Our first question comes from the line of Joel Sendek from Lazard Capital Markets. Please proceed.

Joel Sendek - *Lazard Capital Markets - Analyst*

Thanks a lot. Two questions. First is, can you go over again why the Retavase sales were down, and can you tell us whether the Cardene and Busulfex, the revenues from those drugs increased sequentially in the fourth quarter versus the third quarter? Thanks.

Mark McDade - *PDL BioPharma - CEO*

Second question first. The answer is yes, Joel, and on Retavase, just to be clear, we missed slightly more than a month of sales because, due to some delays related to changing over the label from Centocor, who used to market the drug to the new one that reflected ESP Pharma at the time. There was an unexpected delay, and therefore at our end a stockout of Retavase, so we were not able to ship to the wholesalers. I can—

Joel Sendek - *Lazard Capital Markets - Analyst*

Does that mean that –

Mark McDade - - *PDL BioPharma - CEO*

Sorry?

Joel Sendek - *Lazard Capital Markets - Analyst*

Sorry, I'm just wondering whether there'll be pent-up demand here in the first quarter that would impact the sales of Retavase would have otherwise happened in the fourth quarter as a result?

Mark McDade - *PDL BioPharma - CEO*

I think probably not, is my guess. The biggest impact was that inventory levels in the trade went down to very, very low levels, and we are building that back up.

Joel Sendek - *Lazard Capital Markets - Analyst*

Okay. All right. Thank you.

Mark McDade - *PDL BioPharma - CEO*

Okay.

Operator

Thank you. Our next question comes from the line of Craig Parker from Lehman Brothers. Please proceed with your question.

Craig Parker - *Lehman Brothers - Analyst*

Hi, Mark. I just wanted to focus in a little more on the product sales guidance. If I just picked the mid-point and look at the third and fourth quarter next year over the third and fourth of this year, which I think is the relevant way to look at it, growth is something like 18, 18.5%. Is that sort of the right way to think about the longer-term growth for the ESP product?

Mark McDade - *PDL BioPharma - CEO*

No, we continue to believe in 25% as our basic guidance for ‘06, ‘07, and ‘08, Craig. So I’d guess you’re probably at the low end.

Craig Parker - *Lehman Brothers - Analyst*

I guess that’s a backwards way of asking if you consider that guidance to be fairly conservative, because that guidance is inconsistent with 25%. Again, picking relevant periods, meaning quarters where you’ve reported a full quarter of sales, third and fourth quarter ‘05 compared to third and fourth quarter ‘06 that would be implied or you’re saying that your sales are going to be quite back-end loaded in 2006?

Mark McDade - *PDL BioPharma - CEO*

Well, again, since we don’t have the benefit yet of a full year, and that’s why we’re actually going to have the business updated in May to kind of’ break down how the products are doing, I’d say obviously we do expect scale-up quarter by quarter so that trend should be larger. Is our guidance conservative? Again, the guidance that we’ve given is intended to be year over that multiple time year period, so from 2006 to 2008, Craig.

Craig Parker - *Lehman Brothers - Analyst*

Okay. Thanks, Mark.

Mark McDade - *PDL BioPharma - CEO*

Okay.

Operator

Thank you. Our next question comes from the line of Bret Holley from CIBC World Markets. Proceed with your question.

Bret Holley - *CIBC World Markets - Analyst*

I’ve got the question of the daclizumab trial and MS and what were the reasons for stopping the trial before the — planned number of patients were enrolled in the combo trial? And then how the trial going

forward in monotherapy and are you going to need additional trials in combination with your formulation to get an idea of where you would go in Phase 3 for combination therapy?

Steven Benner - *PDL BioPharma - Chief Medical Officer*

The real reason to stop the trial with less than the full accrual for the combination trial was that we felt we would have sufficient patients to be able to determine whether or not we were seeing the same kinds of activity that had been previously observed in the open-label studies, but we wanted to get additional dose finding information using the PDL-manufactured antibody, which is what's going to be used in the monotherapy trial. So we wanted to have that dose range finding information with our antibody, and we believe that the monotherapy trial could guide further combination trials in terms of the appropriate dosing. So we don't think that there would be a need to repeat, should we take combination further. The other thing I would want to mention is that we also felt here that this was an opportunity for us to take advantage of the strength of our collaborator Biogen Idec, who we feel can efficiently complete a monotherapy trial, where as when we considered that alone prior to beginning any studies, felt it might be difficult for PDL.

Bret Holley - *CIBC World Markets - Analyst*

Great. Thanks a lot, Steve.

Operator

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

Jason Zhang - *Prudential Equity Group - Analyst*

Thanks. Steve, just wanted to follow up on your comments about the open-end [inaudible] wonder what is holding you up [inaudible] and I'm wondering why exactly [inaudible].

Steven Benner - *PDL BioPharma - Chief Medical Officer*

Jason, you're breaking up a little bit on the question, but I think I know where you're headed, so I'll respond. We had wanted to start a trial in— by the end of the first quarter, and the team has been on track, the IND was filed before the end of last year, 2005, and that study would be up and ready to go, but we've also received some comments from the FDA with regards to the trial design, and we're very interested in making sure that we perform a trial that will suit the needs of the agency, so we're going to have those discussions which will be taking place very soon before we actually start enrolling patients into that trial. So we don't at this point have any formal changes to the time line. We think that the upcoming FDA discussion will resolve any issues with regards to trial design.

Jason Zhang - *Prudential Equity Group - Analyst*

Will the discussion change your protocol as you have at least told us before?

Steven Benner - *PDL BioPharma - Chief Medical Officer*

It might. We need to have that discussion with the agency before we know whether or not we'll be just making minor modifications to the current trial or more substantial changes.

Jason Zhang - *Prudential Equity Group - Analyst*

What about patient [inaudible]

Steven Benner - *PDL BioPharma - Chief Medical Officer*

At this time we have no changes to predict. We'll get back to you after we've been able to clarify with the agency what we think are the best steps for the U.S. trial and to get that underway as soon as possible.

Jason Zhang - *Prudential Equity Group - Analyst*

Thanks.

Operator

Thank you. Our next question comes from the line of Phil Nadeau from Cowen. Please proceed.

Phil Nadeau - *SG Cowen - Analyst*

Good afternoon. Congratulations on a successful 2005. My question's actually on the visilizumab Phase 2-3, but I think you said it just began. First, did I hear you correctly in saying that that study's underway? And second, is the protocol for that study the same as what you said at your R&D Day last fall?

Steven Benner - *PDL BioPharma - Chief Medical Officer*

Yes, that trial is open, and it's begun accruing patients, and the trial design is the same as we discussed at the R&D Day, so it's a 150-patient randomized trial in patients that have I.V. steroid refractory ulcerative colitis.

Phil Nadeau - *SG Cowen - Analyst*

And have you discussed what exactly the DSMB is going to be reviewing, and what the trigger is that you need to see to start that second Phase 3 trial?

Steven Benner - *PDL BioPharma - Chief Medical Officer*

We have not disclosed that in any detail what the DSMB will be doing is looking at the safety profile to make sure that's consistent with the previous experience and that we are detecting enough difference between the visilizumab treated patients and the placebo-treated patients that it would be likely that the study could produce a positive result.

Phil Nadeau - *SG Cowen - - Analyst*

Okay, and will your go or no go decision on the Phase 3 be dependent simply on this Phase 2-3 continuing? Meaning are you going to get any of the DSMB's analysis or data before you make your decision or is the go decision from the DSMB good enough for you to go with your Phase 3?

Steven Benner - *PDL BioPharma - Chief Medical Officer*

That is correct. We will not have access to any of this data, and that allows us to complete the initial study, what we've called the Phase 2-3, as a Phase 3 so that all the patients enrolled in the initial study will contribute to the Phase 3 analysis. A positive report from the DSMB that they believe it's appropriate for that trial to continue will be our trigger for starting the second Phase 3.

Phil Nadeau - *SG Cowen - Analyst*

Okay. Great, thanks a lot.

Steven Benner - *PDL BioPharma - Chief Medical Officer*

And just to add one other point, we'll of course notify you when that takes place.

Phil Nadeau - *SG Cowen - Analyst*

Perfect. Thank you.

Operator

Thank you. Our next question comes from the line of Eric Hoffman from JP Morgan. Please proceed with your question.

Eric Hoffman - *JP Morgan - Analyst*

Hi. Thank you for taking my questions and congratulations on a successful 2006. My two questions are on our antibody royalty stream. First is, does your guidance include any additional products that could potentially reach the market in 2006, such as Tysabri or Lucentis, and number 2, on the DNA royalty rate step-down for the U.S. sales, has the first threshold level been reached? As I understand it, it was not reached as of last quarter, thanks.

Mark McDade - *PDL BioPharma - CEO*

So on your first question, Eric— thanks for calling in— the answer is no. We continue to guide consistent with the past several years; that is for products that are not approved indications, we don't include that to the best of our ability, and for unapproved agents or agents that are withdrawn from the market for one reason or another, we have not included those in our guidance as well. It's our belief that dealing with guidance in that fashion allows for upside events rather than downside events if we did build that into our guidance, and also as we talked about in the past, since those royalties provide us a significant chunk of our operating expense, it helps us in budgeting if we are a bit more conservative in those top-line estimates. Your second question with regard to DNA, did I— could you perhaps repeat it? It has to do with the DNA bulk discount, but I wasn't quite certain what your question was referring to, Eric.

Eric Hoffman - *JP Morgan - Analyst*

Sure. As I understand it, the aggregate Genentech sales in the U.S. had not yet triggered the first threshold as of last quarter, which is I think something you disclosed, so I was wondering if that first threshold has been triggered by the full-year sales?

Mark McDade - *PDL BioPharma - CEO*

We do not believe so.

Eric Hoffman - *JP Morgan - Analyst*

Thanks a lot

Mark McDade - *PDL BioPharma - CEO*

Okay.

Operator

Thank you. Our next question comes from the line of Tom McGahren from Merrill Lynch. Please proceed with your question.

Tom McGahren - *Merrill Lynch - Analyst*

With regard to Nuvion, you mentioned that you were possibly starting a study in pediatric ulcerative colitis, maybe one in multiple sclerosis this year, is that still on track or still possible?

Steven Benner - *PDL BioPharma - Chief Medical Officer*

We are considering starting additional trials, including pediatric populations as well as retreatment studies and those are still on schedule. We haven't made a final commitment as to whether or not we'll be starting an MS pilot study this year or not for daclizumab. Our focus is predominantly on the lead indication which is IV steroid refractory ulcerative colitis.

Operator

Thank you. Our next question comes from the line of Craig Parker from Lehman Brothers. Please proceed with your follow-up question.

Craig Parker - *Lehman Brothers - Analyst*

Hi, thanks a lot for taking the follow-up. Mark, I'm sorry, I just missed your statement about the R&D

reimbursement revenue, 60 to 70. You said 40 million could be expected from, was it just Biogen Idec or Biogen Idec plus Roche?

Mark McDade - *PDL BioPharma - CEO*

We said both partners. So that's the multiple programs under Biogen Idec and both the asthma and the transplant maintenance that we do expect will be starting late in the year, Craig.

Craig Parker - *Lehman Brothers - Analyst*

Ok. And sounds like there's not much of a queue, maybe I can ask a second question. Mark, I guess I'm interested in your philosophy about EBITDA being an appropriate metric, particularly with the depreciation portion, because obviously you guys have surveyed the landscape and no one else is reporting that way, and while other people may be excluding stock options and amortization, I don't know of anyone else who's excluding interest taxes or depreciation.

Mark McDade - *PDL BioPharma - CEO*

Well, okay, let me dive in and briefly explain. No you haven't opened the box. I think it's pretty clear, the '06 is very different financially for PDL than '05 and any prior year because our plant opens up for the first time, and so if you were looking and you were not informed as to any of the details of our business and you saw an aberration in expenses to the tune of $25 to $30 million, the average person might be puzzled as to what's going on, and yet, those expenses are tied and they're non-cash, directly to a brand new plant that's coming up to speed in the middle of 2006. On top of that, interest expense and income is relatively neutral, so I think for the time being, that that's not a significant item. And then the third adjustments we make relate to amortization tied to the acquisitions that— of value-adding pieces that we believe again, since they're non-cash, don't reflect how the business is operating from a more purely financial perspective. So I guess from at least my view as the CEO of the Company, that's really the philosophy that we're trying to embody in our newly-stated financials, Craig, going forward.

Craig Parker - *Lehman Brothers - Analyst*

But just to be clear, the depreciation, you're going to exclude is all depreciation, not just the depreciation from that facility?

Mark McDade - *PDL BioPharma - CEO*

Yes, but the bulk of it, more than 2/3 of that figure is the brand new plant, and so you'd have this aberration that if you didn't adjust for it otherwise.

Craig Parker - *Lehman Brothers - Analyst*

And so when do you go back?

Mark McDade - - *PDL BioPharma - CEO*

We don't.

Craig Parker - *Lehman Brothers - Analyst*

Okay. Thank you.

Mark McDade - *PDL BioPharma - CEO*

Okay.

Operator

Thank you. [OPERATOR INSTRUCTIONS]. Our next question comes from the line of Katherine Xu from Pacific Growth Equities. Please proceed with your question.

Katherine Xu - *Pacific Growth Equities - Analyst*

Thank you. My question is regarding the Nuvion Phase 2-3. My understanding is that the trial has been open for a while and the dosing in the first patient hasn't started yet or you guys would already put out a press release. Just wondering, is there anything of note with regard to this seemingly delay?

Mark McDade - *PDL BioPharma - CEO*

No, there's no delay. The study started on as scheduled and the first patient's been dosed.

Katherine Xu - *Pacific Growth Equities - Analyst*

Okay. Thank you.

Operator

Thank you Ms. Knoefler. We are showing no further questions at this time. I will now turn the conference back to you.

Ami Knoefler - *PDL BioPharma - Senior Director, Investor and Corporate Relations*

Excellent. Thank you. Before we close, I thought it would be helpful to let you know that we'll be giving several presentations in the coming weeks, these include the Citigroup Conference in Washington on March 1st, the SG Cowen Conference in Boston March 9, and the JMP Securities conference in San Francisco also on March 9, and the Lehman Brothers Conference in Miami on March 10. Also, for the first time in early May, following the release of our first quarter results, we plan to conduct a business update for Wall Street to review the commercial strategies and life cycle management plans for our marketed products, including Cardene I.V., Retavase, and I.V. Busulfex, as well as to discuss the opportunities we see for our more advanced pipeline programs. Please look to our website and future press releases for additional information on the business update in the very near future. We look forward to seeing many of you at these events and invite you to contact us for further details about any of these programs. Please also contact Investor Relations with your follow-up questions regarding today's press release and conference call. Thank you and good afternoon.

Operator

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