

PDL BIOPHARMA, INC.
Form 8-K
August 19, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

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

Date of report (date of earliest event reported):

August 18, 2008

PDL BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-19756
(Commission File No.)

94-3023969
(I.R.S. Employer Identification
No.)

1400 Seaport Boulevard

Redwood City, California 94063
(Address of principal executive offices)

Registrant's telephone number, including area code:
(650) 454-1000

Edgar Filing: PDL BIOPHARMA, INC. - Form 8-K

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 1.01 Entry Into a Material Definitive Agreement.

On August 18, 2008, PDL BioPharma, Inc. (PDL) and Bristol-Myers Squibb Company (BMS) entered into a Collaboration Agreement (the Agreement) regarding the global development and commercialization of PDL's anti-CS1 antibody, elotuzumab (previously known as HuLuc63).

Pursuant to the terms of the Agreement, BMS would pay to PDL an upfront cash payment of \$30 million and would receive development and marketing rights to elotuzumab and an option to expand the collaboration to include PDL241, another anti-CS1 antibody. PDL also could receive additional payments from BMS of up to \$480 million in development and regulatory milestones and up to \$200 million in sales-based milestones for elotuzumab in multiple myeloma and other potential oncology indications.

If BMS exercises its option to expand the collaboration to include PDL241, upon completion of pre-agreed preclinical studies, PDL would receive an additional cash payment of \$15 million and could receive additional development and regulatory milestone payments of up to \$230 million and sales-based milestone payments of up to \$200 million.

BMS would fund 80 percent of the worldwide development costs of elotuzumab and PDL241, should it be included in the collaboration, and PDL would fund the remainder 20 percent of worldwide development costs. BMS and PDL would share profits on sales of elotuzumab and PDL241, should it be included in the collaboration, in the U.S., with PDL receiving a higher portion of the profit share than represented by its share of funding. PDL would receive royalties on net sales of elotuzumab and PDL241, should it be included in the collaboration, outside the U.S.

PDL would complete the ongoing phase 1 elotuzumab program and provide support for phase 2 studies and BMS would otherwise lead global development activities.

BMS has the right to terminate the Agreement without cause on a product by product and region by region basis with advance written notice.

The closing of the transaction is subject to antitrust clearance under the Hart-Scott-Rodino Act and other customary regulatory approvals.

A copy of the joint press release issued on August 19, 2008 by PDL and BMS announcing the Agreement (the Joint Release) is filed hereto as Exhibit 99.1 and incorporated herein by reference.

Forward-Looking Statements

Edgar Filing: PDL BIOPHARMA, INC. - Form 8-K

This Current Report and the Joint Release contain forward-looking statements, including regarding PDL's potential receipt of an upfront cash payment, a potential option payment, development, regulatory and sale-based milestone payments, a share of profits and royalties. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those, express or implied, in these forward-looking statements. For example:

- PDL would not be entitled to receive the \$30 million upfront cash payment or any other payments under the collaboration agreement if antitrust authorities do not clear the collaboration transaction between PDL and BMS under applicable antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976;

- BMS may not elect to exercise its option to include PDL241 in the collaboration, even if pre-clinical testing demonstrates the development potential of PDL241; and

- PDL's rights to elotuzumab-related milestone payments, PDL241-related milestone payments (should BMS elect to include PDL241 in the collaboration), share of profits and royalties are subject to the successful achievement of numerous development, regulatory and sales milestones, which may be delayed or not achieved for a variety of reasons, including because:

- Elotuzumab is an early-stage development product, which has not been extensively tested in humans, and PDL241 is a preclinical candidate, which has not been tested in humans, and additional clinical studies

would need to be successfully conducted to demonstrate that either elotuzumab or PDL241 is safe and effective as a human therapeutic;

- Delays in contracting with clinical sites, slow enrollment rates, lack of availability of clinical materials or safety or manufacturing issues could adversely impact the development of elotuzumab or PDL241;
- Even if elotuzumab or PDL241 is successfully developed through pivotal studies, the parties may not be able to meet applicable regulatory standards or regulatory authorities may fail to approve the marketing of elotuzumab; and
- Even if elotuzumab or PDL241 is approved for marketing, PDL's receipt of a share of profits, royalties or any of the sales-related milestones could be adversely impacted by the lack of market penetration, availability of drug supply, changes in the markets for these products due to alternative treatments, other actions by competitors or regulatory actions.

In addition, most of the potential payments to PDL, even if made, would occur a number of years in the future and the present value of these future payments would be less than what may be implied by these forward-looking statements. Other factors that may cause PDL's actual results to differ materially from those expressed or implied in these forward-looking statements are discussed in PDL's filings with the Securities and Exchange Commission (SEC), including the Risk Factors sections of PDL's annual and quarterly reports filed with the SEC. PDL expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein or in the Joint Release to reflect any change in PDL's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based for any reason, except as required by law, even as new information becomes available or other events occur in the future. Each forward-looking statement in this Current Report or the Joint Release is qualified in its entirety by this cautionary statement.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Joint Press Release issued by PDL BioPharma, Inc. and Bristol-Myers Squibb Company on August 19, 2008.

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: August 19, 2008

PDL BioPharma, Inc.

By:

/s/ Francis Sarena
Francis Sarena
Vice President, General Counsel and Secretary