

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2006-01-05** | Period of Report: **2006-01-05**  
SEC Accession No. **0001002637-06-000003**

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FILER

**MILLENNIUM PHARMACEUTICALS INC**

CIK: **1002637** | IRS No.: **043177038** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **000-28494** | Film No.: **06513488**  
SIC: **2834** Pharmaceutical preparations

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 5, 2006

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**MILLENNIUM PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**0-28494**  
(Commission file number)

**04-3177038**  
(IRS Employer  
Identification No.)

**40 Landsdowne Street**  
**Cambridge, Massachusetts 02139**  
(Address of principal executive offices) (zip code)

**(617) 679-7000**  
(Registrant's telephone number, including area code)

**Not applicable**  
(Former name or former address if changed since last report)

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

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

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

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

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

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**Item 2.02 Results of Operations and Financial Condition.**

On January 5, 2006, Millennium Pharmaceuticals, Inc. issued a press release to report selected unaudited financial results for the year ended December 31, 2005 and to provide information about its goals for 2006. The full text of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information in this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

The attached press release contains non-GAAP financial measures. These non-GAAP measures should be considered in addition to, not as a substitute for, or superior to other measures of the Company’s financial position prepared in accordance with generally accepted accounting principles (GAAP).

Specifically, the attached press release discusses non-GAAP net income and non-GAAP profitability, which are non-GAAP financial measures. With respect to forward-looking information presented on a non-GAAP basis, other than amortization expenses of approximately \$34 million in each of 2005 and 2006, restructuring charges of between \$80 million and \$85 million in 2005 and between \$25 million and \$30 million in 2006 and stock based compensation expense of between \$40 million and \$50 million in 2006, the Company is unable to provide a quantitative reconciliation because the items that would be excluded are difficult to predict and estimate and are primarily dependent on future events.

The Company’s management uses these non-GAAP financial measures to gain a better understanding of the Company’s core operating results and future prospects, consistent with how management measures and forecasts the Company’s performance, especially when comparing such results to previous periods or forecasts or to those of the Company’s competitors. These measures are also used by the Company’s management in their financial and operating decision-making and for compensation purposes.

These non-GAAP measures exclude certain non-operational and restructuring charges, non-cash charges and specified other charges that are included in the most directly comparable GAAP measures. The Company excludes these items because it believes they are outside of the Company’s normal operations and, in certain cases, are difficult to forecast accurately for future periods. Specifically, on both a historic and a forward-looking basis, these non-GAAP measures exclude:

Costs associated with the Company’s 2005 strategic refinement and restructuring, such as reducing overhead and consolidating facilities, resulting from the restructured relationship between Schering-Plough and the Company for INTEGRILIN® (eptifibatide) Injection and the reduction in the Company’s inflammation discovery programs. The Company believes that the costs related to these restructuring activities are not indicative of the Company’s normal operating costs.

Costs associated with the Company’s 2003 restructuring effort, such as reducing overhead and consolidating facilities. The Company believes that the costs related to these restructuring activities are not indicative of the Company’s normal operating costs.

Expense associated with the amortization of acquisition-related intangible assets because a significant portion of the purchase price for acquisitions may be allocated to intangible assets that have lives of two to 13 years. Exclusion of the amortization expense allows comparisons of operating results that are consistent over time for both the Company’s newly acquired and long-held businesses and with both acquisitive and non-acquisitive peer companies.

Costs associated with the Company’s debt financing activities such as amortization on capitalized professional and banking fees and charges related to the fair value of the put premiums the Company has

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placed on its convertible notes because the Company considers these costs to be nonoperational and nonrecurring and therefore not necessarily indicative of the Company’s future financial commitments.

Expense associated with stock-based compensation related to stock options, the Company's employee stock purchase plan and restricted stock because the Company believes that including this expense could be misleading in the comparison of the Company's financial results to previous periods and does not provide meaningful insight into the Company's ongoing operations. Additionally, because of varying available valuation methodologies, subjective assumptions and the variety of award types, the Company believes that the inclusion of stock-based compensation could create the potential for misleading comparisons of the Company's operating results to its competitors.

**Item 9.01 Financial Statements and Exhibits.**

(c) Exhibits

See Exhibit Index attached to this Current Report on Form 8-K.

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**SIGNATURE**

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.

MILLENNIUM PHARMACEUTICALS, INC.  
(Registrant)

Date: January 5, 2006

By /s/ MARSHA H. FANUCCI

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Marsha H. Fanucci  
Senior Vice President and Chief Financial Officer

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**EXHIBIT INDEX**

| <u>Exhibit No.</u> | <u>Description</u>  |
|--------------------|---|
| 99.1               | Press Release of Millennium Pharmaceuticals, Inc. dated January 5, 2006 |

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**FOR RELEASE THURSDAY, JANUARY 5, 2006 at 4:01 PM EST**

**Contacts:**

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**MILLENNIUM DETAILS STRATEGIC DRIVERS FOR PROFITABLE GROWTH AND 2006 GOALS; HIGHLIGHTS 2005 ACCOMPLISHMENTS**

CAMBRIDGE, Mass., January 5, 2006 – Millennium Pharmaceuticals, Inc. (Nasdaq: MLNM) today announced the Company's 2006 goals and financial outlook as well as key strategic 2005 accomplishments, which will be detailed in a presentation at the 24th Annual JPMorgan Healthcare Conference on January 11, 2006 in San Francisco. Millennium has emerged from 2005 a stronger, more focused company and remains on track to achieve non-GAAP profitability(1) in 2006. Financial guidance for 2006 is:

U.S. net product sales for VELCADE® (bortezomib) for Injection are forecasted to be in the range of \$225 to \$250 million, a 17 to 30 percent increase over 2005

Royalty revenue is expected to be in the range of \$115 to \$125 million

Operating expenses, consisting of both research and development and selling, general and administrative expenses, are anticipated to be approximately \$425 million, a 30 percent decrease from full year 2004 results

Non-GAAP net income is projected to be up to \$5 million

GAAP net loss is expected to be in the range of \$95 to \$115 million(1)

Cash, cash equivalents and marketable securities at the end of the year are anticipated to be greater than \$500 million

“This past year was an important year for Millennium. We sharpened our focus on the key drivers for profitable growth,” said Deborah Dunsire, M.D., president and chief executive officer of Millennium. “VELCADE, the critical revenue driver, remains the market leader in relapsed multiple myeloma, and continues to demonstrate its potential in front-line multiple myeloma as well as in treating other hematologic cancers and solid tumors. Our growth prospects are further evidenced by a rapidly advancing clinical pipeline of novel products.”

Key strategic accomplishments in 2005 included:

U.S. approval of a supplemental new drug application (sNDA) for VELCADE for multiple myeloma patients who have received at least one prior therapy

Achieving VELCADE U.S. net product sales of \$192 million for the full year 2005, a 34 percent increase over 2004

Successful transition of the Company's leadership with a new president and CEO

Restructuring the collaboration for INTEGRILIN® (eptifibatide) Injection to optimize growth

Refining the strategic focus; shifting resources to the oncology discovery and commercial organizations

Advancing the pipeline including two new product candidates from the Company's discovery engine that entered the clinic, and achieving several other clinical milestones

Following are the Company's goals for reaching non-GAAP profitability in 2006 and sustaining growth beyond.

## Products

Millennium expects to continue to grow VELCADE sales 17 to 30 percent over 2005 by:

- Completing the deployment of an expanded sales force

- Increasing educational efforts on VELCADE single-agent survival benefit, combinability with other agents, well-characterized safety profile and the importance of eight cycles of therapy

Together with VELCADE co-development partner Johnson & Johnson Pharmaceutical Research & Development, L.L.C, the Company also plans to:

- Continue to advance three registration-enabling trials in the front-line multiple myeloma setting and further data publications from investigator-initiated trials in support of compendia listing for reimbursement

- File an sNDA in the second half of the year for relapsed mantle cell lymphoma

- Initiate a phase III study of VELCADE based therapy in patients with relapsed follicular lymphoma, an indolent form of non-Hodgkin's lymphoma

## Pipeline

Millennium will strive to progress the pipeline of eight molecules in clinical and advanced pre-clinical development, four of which were discovered by Millennium scientists, and reach key strategic decision points on several molecules or indications including:

- Advancing two new molecular entities from the Company's discovery organization to development candidate status

- Making decisions on whether or not to further the development of at least two clinical programs

## Partnerships and Profits

While additional partnerships are not critical to achieving non-GAAP profitability in 2006, strategic partnerships will remain an integral component of the business strategy in driving the growth agenda. To sustain future profitability, the Company will continue to strive for improved efficiencies, productivity and fiscal discipline.

The Company will discuss these goals in more detail with investors during a live webcast and conference call tomorrow, Friday, January 6, 2006 at 8:30 a.m. EST. The live webcast can be accessed by visiting the Investors section of the Company's website, [www.millennium.com](http://www.millennium.com). Following the webcast, an archived version of the call will be available at the same address for 30 days. Dr. Dunsire will present additional detail on January 11, 2006 at the JPMorgan 24th Annual Healthcare Conference. The presentation will be webcast live at 10:30 a.m. PST (1:30 p.m. EST) and may be accessed by visiting the Investors section of the Company's website, [www.millennium.com](http://www.millennium.com).

## About VELCADE

VELCADE is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy. VELCADE is contraindicated in patients with hypersensitivity to bortezomib, boron, or mannitol. VELCADE should be administered under the supervision of a physician experienced in the use of antineoplastic therapy.

Risks associated with VELCADE therapy include new or worsening peripheral neuropathy, hypotension observed throughout therapy, cardiac disorders, gastrointestinal adverse events, thrombocytopenia and tumor lysis syndrome. Women of childbearing potential should avoid becoming pregnant while being treated with VELCADE.

In 331 patients who were treated with VELCADE in a phase III study, the most commonly reported adverse events were asthenic conditions (61%), diarrhea (57%), nausea (57%), constipation (42%), peripheral neuropathy (36%), vomiting (35%), pyrexia (35%), thrombocytopenia (35%), psychiatric disorders (35%), anorexia and appetite decreased (34%), parasthesia (27%), dysesthesia (27%), anemia and headache (26%), and cough (21%). Fourteen percent of patients reported at least one episode of grade 4 toxicity; the most common grade 4 toxicities were thrombocytopenia (4%), neutropenia (2%), and hypercalcemia (2%). A total of 144 patients on VELCADE (44%) reported serious adverse events (SAEs) during the study. The most commonly reported SAEs were pyrexia (6%), diarrhea (5%), dyspnea, pneumonia (4%), and vomiting (3%).

VELCADE is being co-developed by Millennium Pharmaceuticals, Inc. and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Millennium is responsible for commercialization of VELCADE in the U.S.; Janssen-Cilag is responsible for commercialization in Europe and the rest of the world. Janssen Pharmaceutical K.K. is responsible for commercialization in Japan. Outside the United States, VELCADE is approved as a second-line treatment. It is indicated as a monotherapy for use in patients with progressive multiple myeloma who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation.

For more information about VELCADE clinical trials, patients and physicians can contact the Millennium Medical Product Information Department at 1-866-VELCADE (1-866-835-2233).

### **About Millennium**

Millennium Pharmaceuticals, Inc., a leading biopharmaceutical company based in Cambridge, Mass., markets VELCADE, a novel cancer product, and has a robust clinical development pipeline of product candidates. The Company's research, development and commercialization activities are focused in two therapeutic areas: oncology and inflammation. By applying its knowledge of the human genome, its understanding of disease mechanisms and its industrialized drug discovery platform, Millennium is seeking to develop breakthrough products. The Company's website is [www.millennium.com](http://www.millennium.com).

*This press release contains "forward-looking statements," including statements about the Company's growth, future operating results, discovery, development of products and strategic alliances. Various important risks may cause the Company's actual results to differ materially from the results indicated by these forward-looking statements, including: adverse results in its drug discovery and clinical development programs; failure to obtain patent protection for its discoveries; commercial limitations imposed by patents owned or controlled by third parties; the Company's dependence upon strategic alliance partners to develop and commercialize products and services based on its work; difficulties or delays in obtaining regulatory approvals to market products and services resulting from its development efforts; product withdrawals; competitive factors; difficulties or delays in manufacturing the Company's products; government and third party reimbursement rates; the commercial success of VELCADE and INTEGRILIN; achieving revenue consistent with internal forecasts; and the requirement for substantial funding to conduct research and development and to expand commercialization activities. For a further list and description of the risks and uncertainties the Company faces, see the reports it has filed with the Securities and Exchange Commission. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

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Editor's Note: This release is available under the Media section on the Company's website at [www.millennium.com](http://www.millennium.com).

(1) Non-GAAP net income and non-GAAP profitability are non-GAAP financial measures. With respect to forward-looking information presented on a non-GAAP basis, other than amortization expenses of approximately \$34 million in each of 2005 and 2006, restructuring charges of between \$80 million to \$85 million in 2005 and between \$25 million and \$30 million in 2006 and stock based compensation expense of between \$40 million and \$50 million in 2006, the Company is unable to provide a quantitative reconciliation because the items that would be excluded are difficult to predict and estimate and are primarily dependent on future events. Please see the Form 8-K furnished on January 5, 2006, by the Company to the Securities and Exchange Commission for a discussion of why the Company believes these non-GAAP measures are useful to investors and the additional purposes for which management uses these measures.