

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

Current report filing

Filing Date: **2005-05-02** | Period of Report: **2005-04-29**  
SEC Accession No. **0001104659-05-019588**

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### FILER

#### **NITROMED INC**

CIK: **927829** | IRS No.: **223159793** | State of Incorpor.: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **000-50439** | Film No.: **05789649**  
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): **April 29, 2005**

**NITROMED, INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation)

**000-50439**  
(Commission File Number)

**22-3159793**  
(IRS Employer  
Identification No.)

**125 Spring Street**  
**Lexington, Massachusetts**  
(Address of Principal Executive  
Offices)

**02421**  
(Zip Code)

Registrant's telephone number, including area code: **(781) 266-4000**

(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:

- 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 8.01. Other Events.**

On April 29, 2005, NitroMed, Inc. ("NitroMed") issued a press release announcing that the U.S. Food and Drug Administration had stated on its website that the Cardiovascular and Renal Drugs Advisory Committee plans to review NitroMed's New Drug Application for the investigational drug BiDil. BiDil is NitroMed's product candidate for the treatment of heart failure in African Americans. The full text of

NitroMed's press release regarding the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of NitroMed, Inc. dated April 29, 2005

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2

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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.

Date: May 2, 2005

NITROMED, INC.

By: /s/ Lawrence E. Bloch, M.D., J.D.  
Lawrence E. Bloch, M.D., J.D.  
Chief Financial Officer, Chief Business  
Officer, Treasurer and Secretary

3

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of NitroMed, Inc. dated April 29, 2005

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4

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**For Immediate Release****FDA Schedules Advisory Committee Review of BiDil®**

**LEXINGTON, Mass. April 29, 2005** - NitroMed, Inc. (NASDAQ: NTMD) announced that the U.S. Food and Drug Administration stated on its website today that the Cardiovascular and Renal Drugs Advisory Committee plans to review the Company's New Drug Application (NDA) for the investigational drug BiDil®. BiDil is the Company's product candidate for the treatment of heart failure in African Americans. The Committee meeting is scheduled for June 16<sup>th</sup>, 2005.

Additional information on the advisory committee can be found on the FDA Web site, which may be updated from time to time: [www.fda.gov](http://www.fda.gov)

**About NitroMed, Inc.**

NitroMed is an emerging pharmaceutical company focused on the research, development and commercialization of proprietary pharmaceuticals based on the therapeutic benefits of the naturally occurring molecule nitric oxide. The Company uses its expertise in nitric oxide biology and chemistry in an effort to develop both new pharmaceuticals, as well as safer, more effective versions of existing drugs. Research and development efforts focus on major diseases that are characterized by a deficiency in nitric oxide, such as cardiovascular and inflammatory diseases. BiDil, the Company's lead product candidate, is an orally administered nitric oxide-enhancing medicine being developed for the treatment of heart failure in African Americans. Corporate collaborations are also an element of the Company's business strategy, and NitroMed has an agreement with Boston Scientific to jointly develop nitric oxide-enhanced cardiovascular stents.

**Forward Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: difficulties or delays relating to required regulatory approvals to market and sell BiDil and other factors discussed in its Annual Report on Form 10-K for the Year ended December 31, 2004, which is filed with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

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**Contact:**

Lawrence E. Bloch, M.D., J.D.

NitroMed, Inc.

Chief Financial Officer/Chief Business Officer

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