

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

VION PHARMACEUTICALS INC

CIK: **944522** | IRS No.: **133671221** | State of Incorpor.: **DE** | Fiscal Year End: **1231**
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SIC: **2836** Biological products, (no diagnostic substances)

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**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) **December 10, 2007**

VION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-26534
(Commission File Number)

13-3671221
(IRS Employer Identification No.)

4 Science Park, New Haven, CT
(Address of Principal Executive Offices)

06511
(Zip Code)

Registrant's telephone number, including area code: **(203) 498-4210**

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 8.01. Other Events

On December 10, 2007, Vion Pharmaceuticals, Inc. issued a press release announcing that data from its pivotal Phase II trial of its lead anticancer agent Cloretazine® (VNP40101M) in elderly patients with de novo poor-risk acute myelogenous leukemia (AML) had been presented at the Annual Meeting of the American Society of Hematology in Atlanta, Georgia. A copy of that press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated December 10, 2007.

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.

VION PHARMACEUTICALS, INC.

Date: December 10, 2007

By: /s/ Howard B. Johnson

Name: Howard B. Johnson

Title: President and Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated December 10, 2007.



COMPANY CONTACT: Vion Pharmaceuticals, Inc.

Alan Kessman, Chief Executive Officer

Howard B. Johnson, President & CFO

(203) 498-4210

**Vion Pharmaceuticals Presents Preliminary Data from
its Pivotal Phase II Trial of Cloretazine[®] (VNP40101M) in
Acute Myelogenous Leukemia at ASH Annual Meeting**

NEW HAVEN, CT, December 10, 2007 - VION PHARMACEUTICALS, INC. (NASDAQ CAPITAL MARKET: VION) today announced that data from its pivotal Phase II trial of its lead anticancer agent Cloretazine[®] (VNP40101M) in elderly patients with *de novo* poor-risk acute myelogenous leukemia (AML) had been presented at the Annual Meeting of the American Society of Hematology in Atlanta, Georgia.

Alan Kessman, Chief Executive Officer, said, "We are extremely pleased with these preliminary data. Based on these data at this time, we believe that we have achieved the targeted response rate for this study." He added, "It remains our plan to file a new drug application with the U.S. Food and Drug Administration in 2008 based on the data from this trial and our previous Phase II trial in elderly patients with AML."

The pivotal Phase II trial started in March 2006 and was conducted in 17 sites in North America and Europe. Completion of accrual was achieved in August 2007. The trial remains open at selected sites in order to collect Qt/Qt_c interval data in an electrocardiogram sub-study in accordance with FDA/ICH guidelines.

Patients received induction therapy of 600 mg/m² of Cloretazine[®] (VNP40101M) in a sixty minute-infusion. Second induction was permitted between days 35 and 60 in patients with bone marrow improvement but residual disease. Patients who responded could receive consolidation therapy with a continuous infusion of 400 mg/m² of cytarabine for five days. The primary endpoint of the trial was the overall complete response (CR) rate (including CR and CR_p, a complete response with incomplete platelet recovery). Secondary endpoints were progression-free survival, leukemia-free

survival, overall survival and the toxicity of Cloretazine[®] (VNP40101M) in this patient population.

Data were presented in 80 evaluable patients. The median age of these patients was 73 years (range of 61-87 years). Ninety percent of patients had two or more risk factors associated with a poor prognosis in elderly AML. The most common risk factors were age greater than or equal to 70 (78% of patients), and cardiac and pulmonary dysfunction (60% and 59% of patients respectively). In addition, 49% of patients had unfavorable cytogenetics.

The overall complete response rate was 35% (20 CR and 8 CRp). 93% of responses occurred after first induction treatment. Median overall survival for responders has not yet been reached. The range of days of overall survival for the responders was 53 days to 410 days.

Death within 30 and 42 days of first induction treatment was 15% and 24% respectively. The majority of early deaths were either due to progression of disease or infection. Myelosuppression was the primary toxicity, with febrile neutropenia, pneumonia and sepsis being the most common serious adverse events (greater than or equal to grade 3) considered at least possibly related to therapy. Serious non-hematologic adverse events (greater than or equal to grade 3) considered at least possibly related to therapy occurred in 14% of patients.

Ann Cahill, Vice President of Clinical Development, commented, “The elderly patients on this trial had multiple risk factors which are associated with a poor prognosis in the treatment of AML. We are encouraged by the 35% overall response rate in this group of patients.” Ms. Cahill concluded, “We believe that these preliminary data further reinforce the role that Cloretazine[®] (VNP40101M) can play in this area of unmet medical need.”

Dr. Gary Schiller, Professor of Medicine at the David Geffen School of Medicine at UCLA and a lead investigator on the study, said “The activity demonstrated in this trial appears to confirm the strong signal observed in the first Phase II study of Cloretazine[®] (VNP40101M) in this population. This single agent, single infusion therapy, has the potential to be an important new treatment option for older patients with poor-risk AML.”

The Company will hold a conference call today to discuss the poster at 9:00 a.m. Eastern Time. To participate in the conference call, please dial (866) 356-4123 in the U.S. ((617) 597-5393 for international callers) at least 15 minutes before the start of the call. When prompted for a pass code, please enter 16444471.

An audio webcast of the call will be accessible at www.vionpharm.com. Those who wish to listen to the conference call on the Web should visit the Investor Relations section of the Company's website at least 15 minutes prior to the event broadcast, and follow the instructions provided to assure that the necessary audio applications are downloaded and installed. These programs can be obtained at no charge to the user.

Vion Pharmaceuticals, Inc. is committed to extending the lives and improving the quality of life of cancer patients worldwide by developing and commercializing innovative cancer therapeutics. Vion has two agents in clinical trials. Cloretazine[®] (VNP40101M), a unique alkylating agent, is being evaluated in a Phase II pivotal trial as a single agent in elderly patients with previously untreated *de novo* poor-risk acute myelogenous leukemia. Clinical trials of Cloretazine[®] (VNP40101M) as a single agent in small cell lung cancer, with temozolomide in brain tumors, and with stem cell transplantation in advanced hematologic malignancies, are also being conducted. Triapine[®], a potent inhibitor of a key step in DNA synthesis, is being evaluated in clinical trials sponsored by the National Cancer Institute. For additional information on Vion and its product development programs, visit the Company's Internet web site at www.vionpharm.com.

This news release contains forward-looking statements. Such statements are subject to certain risk factors which may cause Vion's plans to differ or results to vary from those expected, including Vion's potential inability to obtain regulatory approval for its products, delayed or unfavorable results of drug trials, the possibility that favorable results of earlier preclinical studies or clinical trials are not predictive of safety and efficacy results in later clinical trials, the need for additional research and testing, the potential inability to secure external sources of funding to continue operations, the inability to access capital and funding on favorable terms, continued operating losses and the inability to continue operations as a result, and a variety of other risks set forth from time to time in Vion's filings with the Securities and Exchange Commission, including but not limited to the risks attendant to the forward-looking statements included under Item 1A, "Risk Factors" in Vion's Form 10-K for the year ended December 31, 2006 and the Company's Form 10-Q for the quarter ended September 30, 2007. In particular, there can be no assurance as to the results of any of the Company's clinical trials, that any of these trials will continue to full accrual, or that any of these trials will not be discontinued, modified, delayed or ceased altogether. Except in special circumstances in which a duty to update arises under law when prior disclosure becomes materially misleading in light of subsequent events, Vion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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