MEDICINOVA INC
Form 8-K
August 19, 2005

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 16, 2005

MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-51133**	**33-0927979**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4350 La Jolla Village Drive, Suite 950

San Diego, CA 92122

(Address of principal executive offices) (Zip Code)

Registrant s telephone number, including area code: (858) 373-1500

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:

¨ 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 7.01. Regulation FD Disclosure.

On Wednesday, August 17, 2005 (Japanese Standard Time), MediciNova, Inc. (the Company) held a live Japanese language meeting (the Meeting) at Tokyo Shoken Kaikan 9F, 1-5-8 Nihonbashi-Kayabacho, Chuo-ku, Tokyo to discuss the Company s financial results for the six months ended June 30, 2005 and the contents of the Company s report filed with the Osaka Securities Exchange referred to as Kessan Tanshin, which report contained, among other things, the Company s financial results for the first half of 2005 (the Japanese Filing). A translation of the Japanese Filing was filed with the U.S. Securities and Exchange Commission on August 15, 2005 as an exhibit to a current report on Form 8-K. The Meeting was made available by webcast on the Osaka Securities Exchange website promptly following the Meeting. A link was posted to the Company s website to permit access to the webcast.

The content of the Meeting was substantially the same as the content of the Japanese Filing, except the following supplemental information was provided in the Meeting:

2005 Mid-Term Project Development Status Update:

MN-001 (Bronchial asthma) Commencement of patient enrollment under the U.S. Phase II study;

MN-166 (Multiple sclerosis) Commencement of patient enrollment under the E.U. Phase II study;

MN-029 (Solid tumor) Commencement of patient enrollment under the second U.S. Phase I study;

MN-221 (Premature labor) Commencement of patient enrollment under the U.S. Phase I study; and

MN-001 (Interstitial cystitis) Commencement of registration for the U.S. Phase II study.

	Current	Enrollment	Percentage of	2004		2005				2006			
Project	**Stage**	**Target**	**Completion**	**3Q**	**4Q**	**1Q**	**2Q**	**3Q**	**4Q**	**1Q**	**2Q**	**3Q**	**4Q**
MN-001 (Bronchial asthma)	Phase I	120	117%			Phase II Starts			Phase II Completes	Out-licensing			
MN-001 (Interstitial cystitis)	Phase II	291	NA				Phase II Starts					Phase II Completes	
MN-029-1	Phase I	NA	NA					Phase I Completes					
MN-029-2	Phase I	NA	NA			Phase I Starts		Phase I Completes					
MN-305	Phase II	405	19%		Phase II Starts							Phase II Completes	
MN-221	Phase I	40	160%										

				Phase I Starts	Phase I Completes	Phase II Starts (EU)		Phase II Completes (EU)
MN-166	Phase II	300	13%		Phase II Starts			
MN-246	Preclinical	NA	NA				Phase I Starts	

Summary of MN-001 Protocol:

Study Design	A randomized, double-blind, placebo-controlled study evaluating the effects in patients with mild to moderate asthma.
Inclusion Criteria	Mild to moderate asthma: Forced Expiratory Volume in 1 second (FEV1) > 65%; Increase in FEV1 of at least 12% with bronchodilator use over baseline FEV1; Methacholine challenge test with a $PC_{20} \leq$ 8mg/ml.
Dose Regimen	Placebo, 500mg (TID), 750mg (BID), and 750mg (QD) for 4 weeks of treatment.

Enrollment Targets	120 completes with at least 30 subjects per arm.
Efficacy Evaluation - Primary Endpoint	Change from baseline FEV1 after 4 weeks of treatment.
Efficacy Evaluation - Secondary Endpoint	Change in morning and evening peak flow rates, symptoms, and adverse effects.
Method of Analysis	Primary comparison will be between each MN-001 group and placebo. All other pairwise comparisons will be performed as secondary analyses.

The information in this Form 8-K is being furnished and shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. The information in this Form 8-K shall not be incorporated by reference into any registration statement or filing of the Company, except as shall be expressly set forth by specific reference in such a filing.

This report contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include statements regarding the expected progress of the development of the Company s product candidates. These statements are based on certain assumptions made by the Company s management that are believed to be reasonable at the time. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond the control of the Company, including results of clinical studies and other risks and uncertainties, including those described in the Company s filings with the Securities and Exchange Commission. These assumptions, risks and uncertainties could cause the Company s actual results to differ materially from those implied or expressed by the forward-looking statements.

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, thereunto duly authorized.

Dated: August 19, 2005

MEDICINOVA, INC.

By: /s/ Takashi Kiyoizumi
Takashi Kiyoizumi, M.D., Ph.D.
President and Chief Executive Officer