# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 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): July 13, 2009

# MEDICINOVA, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE (State or Other Jurisdiction of Incorporation) 001-33185 (Commission File Number) 33-0927979 (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 (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))

### Item 8.01. Other Events.

On July 13, 2009, MediciNova, Inc. issued a press release (the "Press Release") announcing the proposed final protocol for its Phase II clinical trial (MN-221-CL-007) evaluating the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma. A copy of the Press Release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K being provided under this Item 8.01, including Exhibit 99.1 furnished herewith, is being furnished and shall not be deemed "filed" for any purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such Section. The information in this current report on Form 8-K shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

# Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits.
- 99.1 Press Release dated July 13, 2009.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, MediciNova has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# MEDICINOVA, INC.

Date: July 13, 2009 By: /s/ Shintaro Asako

Name: Shintaro Asako
Title: Chief Financial Officer

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CONTACT: Shintaro Asako Chief Financial Officer Phone: 858-373-1500 E-mail: <u>info@medicinova.com</u>

Rhonda Chiger Rx Communications, LLC Phone: (917) 322-2569 E-mail: <a href="mailto:rchiger@rxir.com">rchiger@rxir.com</a>

### FOR IMMEDIATE RELEASE

# MediciNova Announces Proposed Final Protocol for its Phase II Placebo-controlled Clinical Trial Evaluating MN-221 in Patients with Severe, Acute Exacerbations of Asthma

SAN DIEGO, CA. – July 13, 2009 – MediciNova, Inc., a biopharmaceutical company that is publicly traded on the Nasdaq Global Market (Trading Symbol: MNOV) and the Hercules Market of the Osaka Securities Exchange (Code Number: 4875), today announced the proposed final protocol for its Phase II clinical trial (MN-221-CL-007), which is evaluating the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma. Following a more comprehensive pharmacokinetic/pharmacodynamic (PK/PD) analysis and model of data from previous Phase II clinical trials, it was determined that the dose of 1,200 micrograms of MN-221 administered over one hour may provide greater potential efficacy without conferring additional risk to patients. As such, dosing in the MN-221-CL-007 clinical trial will now compare standardized care only to standardized care plus MN-221 at a dose of 1,200 micrograms administered over one hour rather than at a dose of 250 micrograms administered over 15 minutes, as previously contemplated.

MediciNova has submitted an amendment to the clinical trial protocol for MN-221-CL-007 to the U.S. Food and Drug Administration (FDA) which reflects this dosing regimen and plans to submit the same information to the relevant regulatory authorities outside of

the United States. MediciNova has also communicated this modification to the participating study investigators and clinical sites. MediciNova anticipates patient enrollment to resume within approximately two months and expects to complete enrollment within nine to 12 months from such point in time.

"After completing the more comprehensive PK/PD analysis, we concluded that the dose of 1,200 micrograms of MN-221 given over one hour had the best chance of proving the effectiveness of this promising new potential product for acute exacerbations of asthma. Most importantly, by going to this dose, we do not believe we are conferring additional risks to patients. Our safety analysis also included, in a blinded fashion, the safety data from the limited number of patients who already completed dosing in MN-221-CL-007 at the proposed dosing regimen, said Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova, Inc. "We look forward to resuming the study and anticipate that patient enrollment will accelerate as we approach the peak asthma season in North America."

# About the MN-221-CL-007 Phase II Clinical Trial

MN-221-CL-007 is a randomized, double-blind, placebo-controlled Phase II clinical trial. A total of approximately 35 clinical sites, including the clinical sites rolled-over from the MN-221-CL-006 clinical trial, in North America, Australia and New Zealand will enroll approximately 200 patients into the MN-221-CL-007 clinical trial. Once a patient has received the initial standardized care treatment regimen (consistent with the National Asthma Education and Prevention Program and the Global Initiative for Asthma (GINA) guidelines), the patient will be assessed for response to that treatment. If the patient's forced expiratory volume in one second (FEV<sub>1</sub>) is less than or equal to 50 percent of predicted and the patient meets all other study entry criteria, the patient will be randomized to receive either MN-221 or placebo. Patients enrolled in the study will continue to receive standardized care as needed while receiving an intravenous infusion of MN-221 or placebo. The primary efficacy endpoint will be improvement in FEV<sub>1</sub>.

### **About MN-221**

MN-221 is a highly-selective  $\beta_2$ -adrenergic receptor agonist. Preclinical testing *in vitro* and *in vivo* shows MN-221 to be more selective for the  $\beta_2$ -adrenergic receptor than other  $\beta_2$ -adrenergic receptor agonists commonly used for these asthma attacks. This improved selectivity, coupled with its partial agonist activity at  $\beta_1$ -adrenergic receptors, may result in fewer cardiovascular side effects than are commonly observed with these other agents. MediciNova has developed an intravenous formulation of MN-221 that bypasses the constricted airways to deliver the drug to the lungs. In addition to the data described above MN-221 has been shown to produce significant improvements in mean change in post-infusion (15 minute) FEV<sub>1</sub> from baseline (objective measure of lung function) at doses of 3.5 micrograms/min (p=0.011), and at 10, 16, 30 and 60 micrograms/min (p less than or equal to 0.0001), compared to placebo in stable mild-to-moderate asthma patients (MN-221-CL-004). Administration of MN-221 at a dose of approximately 1,100 micrograms over intervals of one or two hours also produced marked improvement in FEV<sub>1</sub> in patients with moderate-to-severe stable asthma (MN-221-CL-005). In addition, administration of 1,100 micrograms of MN-221 over one hour produced the greatest FEV<sub>1</sub> improvement in patients with stable asthma of the regimens tested in these two studies. Based on an analysis of the data from the recently completed Phase II clinical trial (MN-221-CL-006), doses of 240 micrograms to over 1,100 micrograms of MN-221 administered to subjects with an acute exacerbation of asthma in combination with standard care was associated with improvement in FEV<sub>1</sub> compared to standard care alone and was well tolerated. In addition, a recently completed drug interaction study in dogs found that adding MN-221 by intravenous administration in combination with inhaled albuterol does not add to the heart rate increase associated with inhaled albuterol alone.

MediciNova acquired an exclusive, worldwide (excluding Japan), sublicensable license to MN-221 from Kissei Pharmaceutical Co., Ltd. The intellectual property acquired from Kissei included extensive preclinical and clinical safety data.

### About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company focused on acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, MediciNova holds rights to a diversified portfolio of clinical and preclinical product candidates, each of which MediciNova believes has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope. MediciNova's pipeline includes six clinical-stage compounds for the treatment of acute exacerbations of asthma, multiple sclerosis, asthma, interstitial cystitis, solid tumor cancers, Generalized Anxiety Disorder, preterm labor and urinary incontinence and two preclinical-stage compounds for the treatment of thrombotic disorders.

MediciNova's current strategy is to focus its resources on its two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of multiple sclerosis, and either pursue development independently, in the case of MN-221, or establish a strategic collaboration to support further development, in the case of MN-166. MediciNova will seek to monetize its other product candidates at key value inflection points. For more information on MediciNova, Inc., please visit <a href="https://www.medicinova.com">www.medicinova.com</a>.

Statements in this press release that are not historical in nature, including those related to the progress of the product development program for MN-221 for the treatment of acute exacerbations of asthma, constitute forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding MediciNova's clinical trials supporting safety and efficacy of product candidates and the potential novelty of such product candidates as treatments for disease, plans and objectives for present and future clinical trials and product development, strategies, future performance, expectations, assumptions, financial condition, liquidity and capital resources. These forward-looking statements may be preceded by, followed by or otherwise include the words "believes," "expects," "anticipates,"

"intends," "estimates," "projects," "can," "could," "may," "would," or similar expressions. These forward-looking statements involve a number of risks and uncertainties that may cause actual results or events to differ materially from those expressed or implied by such forward-looking statements. Factors that may cause actual results or events to differ materially from those expressed or implied by these forward-looking statements, include, but are not limited to, the risks and uncertainties inherent in clinical trials and product development and commercialization, such as the uncertainty in results of clinical trials for product candidates, the uncertainty of whether the results of clinical trials will be predictive of results in later stages of product development, the risk of delays or failure to obtain or maintain regulatory approval, the risk of failure of the third parties upon whom MediciNova relies to conduct its clinical trials and manufacture its product candidates to perform as expected, the risk of increased cost and delays due to delays in the commencement, enrollment, completion or analysis of clinical trials or significant issues regarding the adequacy of clinical trial designs or the execution of clinical trials and the timing, cost and design of future clinical trials and research activities, the timing of expected filings with the FDA, MediciNova's failure to execute strategic plans or strategies successfully, MediciNova's collaborations with third parties, the availability of funds to complete product development plans and MediciNova's ability to raise sufficient capital when needed, intellectual property or contract rights, and the other risks and uncertainties described in MediciNova's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2008 and its subsequent periodic reports on Forms 10-Q and 8-K. Undue reliance should not be placed on these forward-looking statements.