

---

**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): July 17, 2013**

---

**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**  
(I.R.S. Employer  
Identification No.)

**4275 EXECUTIVE SQUARE,  
SUITE 650, LA JOLLA, CA**  
(Address of principal executive offices)

**92037**  
(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 17, 2013, MediciNova Inc. (the "Company") updated the slide presentation to be used by the Company at investor meetings. A copy of the revised slide presentation is attached as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Slide presentation of the Company.

**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.

**MEDICINOVA, INC.**

By: /s/ Michael Gennaro  
Michael Gennaro  
*Chief Financial Officer*

Date: July 17, 2013

EXHIBIT INDEX

Exhibit  
No.

Description

99.1

Slide presentation of the Company.



*Developing Novel Therapeutics for  
the Treatment of Serious Diseases  
with Unmet Medical Needs*



# Forward-Looking Statements

Statements in this presentation that are not historical in nature 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 statements regarding MediciNova's clinical trials supporting the safety and efficacy of its product candidates and the potential novelty of such product candidates as treatments for disease, plans and objectives for 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 "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would," or similar expressions. Actual results or events may differ materially from those expressed or implied in any forward-looking statements due to various factors, including the risks of obtaining future partner or grant funding for development of MN-166 and MN-221 and risks of raising sufficient capital when needed to fund MediciNova's operations and contribution to clinical development, risks and uncertainties inherent in clinical trials, including the potential cost, expected timing and risks associated with clinical trials designed to meet FDA guidance and the viability of further development considering these factors, product development and commercialization risks, risks associated with the reliance on third parties to sponsor and fund clinical trials, risks regarding intellectual property rights in product candidates and the ability to defend and enforce such intellectual property rights, the uncertainty of whether the results of clinical trials will be predictive of results in later stages of product development, delays or failure to obtain or maintain regulatory approval, the risk of failure of the third parties upon whom MediciNova relies to perform 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 regulatory authorities; 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 obtain third party funding for programs and 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 MediciNova's annual report on Form 10-K for the year ended December 31, 2012 and its subsequent periodic reports on Forms 10-Q and 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of July 20, 2013. MediciNova disclaims any intent or obligation to update these forward-looking statements.



# MediciNova Highlights

---

- **Two novel product candidates** in clinical development, both with encouraging efficacy and safety data
  - **MN-166 (ibudilast)** for the treatment of drug addiction & progressive MS
    - Licensed from Kyorin Pharmaceuticals
    - Two Phase 2 studies (methamphetamine and opioid addiction)
    - Two progressive MS trials (pending grant funding)
    - Newly-issued patents (addiction and Progressive MS)
  - **MN-221** for the treatment of acute exacerbations of asthma
    - Licensed from Kissei Pharmaceutical Co., Ltd.
    - Had an End of Phase 2 meeting with FDA
    - Newly-issued patent
- **Well-capitalized**
- **Experienced management team**



# MediciNova: Active Programs in Clinical Development

Indication	Preclinical	Phase 1	Phase 2	Phase 3
<b>MN-166, Oral Anti-inflammatory / Neuroprotective Therapeutic</b>				
<b>Methamphetamine Dependence</b> UCLA, Funded by NIDA	Fast Track			
<b>Opioid Dependence</b> Columbia University, Funded by NIDA				
<b>Medication Overuse Headache (MOH)</b> University of Adelaide, Funded by Australian Gov't				
<b>Progressive Multiple Sclerosis</b> Pending Grant Funding				
<b>MN-221, Intravenous Bronchodilator</b>				
<b>Acute Exacerbations of Asthma</b>				



# **MN-221 (bedoradrine):**

## **A Novel Intravenous Treatment for Acute Exacerbations of Asthma**



# MN-221 (bedoradrine) Overview

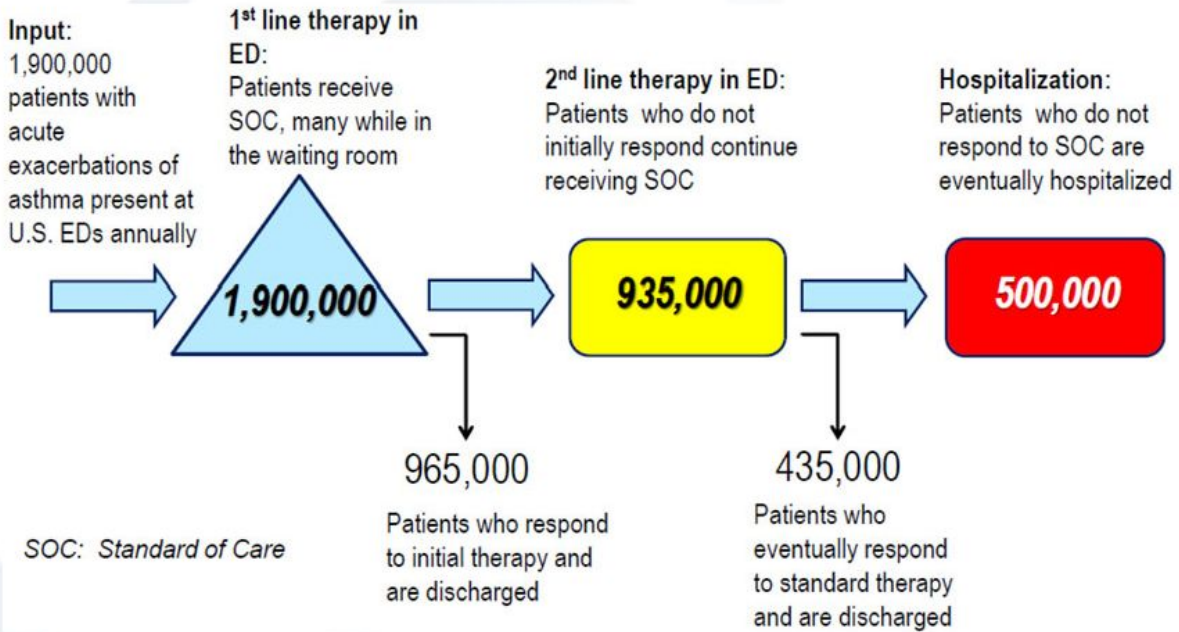
---

- NCE (new chemical entity), small molecule adrenergic receptor agonist in iv form
- In development for the treatment of Acute Exacerbations of Asthma (AEA) adjunctive to standard of care
- Licensed from Kissei Pharmaceutical Co., Ltd.
- Completed four Phase 2 clinical trials in asthma or AEA and two Phase 1b/2a clinical trials in COPD
- New method-of-use patent may significantly extend market exclusivity with patent protection until at least 2030 in U.S.
- Had an End of Phase 2 meeting with FDA



# MN-221 (bedoradrine) Overview

## Acute Asthma Treatment Flow in Emergency Departments in the U.S.



Source: National Center for Health Statistics / CDC, National Hospital Discharge Survey



## Next Steps for MN-221: Based on End of Phase 2 meeting with FDA

---

### 1. API Manufacturing requirements of FDA

- ✓ Kissei, our API supplier, is addressing requirements
- ✓ Approximately 6-month duration

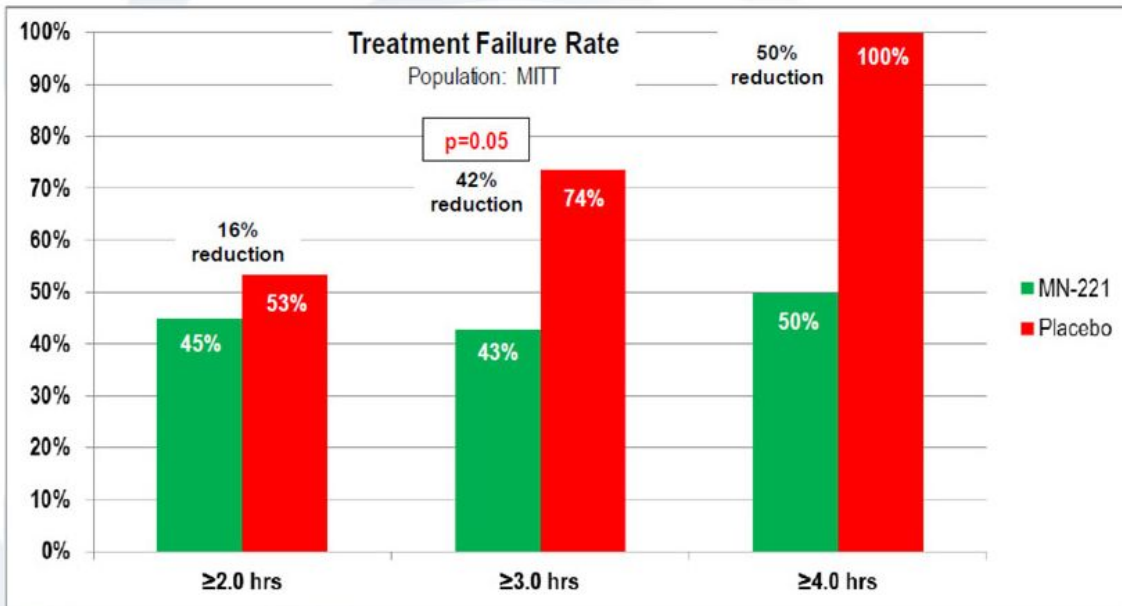
### 2. Clinical development work including:

- ✓ Dose regimen optimization
- ✓ Revision and validation of acute asthma exacerbation trial
  - Primary endpoint will include hospitalization, consistent with FDA guidance



# MN-221: Impact of Dose Timing

Based on Phase 2b data, the ideal time to administer MN-221 is after the patient has not responded to standard of care for more than 3-4 hours.



Note: Treatment Failure is hospitalization or return ER visit due to asthma. Times are time difference between steroid dose and study drug.  
Data is from Phase 2b trial of MN-221 in acute exacerbations of asthma.

# **MN-166 (ibudilast):**

## **A Novel Oral Therapy for the Treatment of Methamphetamine and Opioid Addiction**



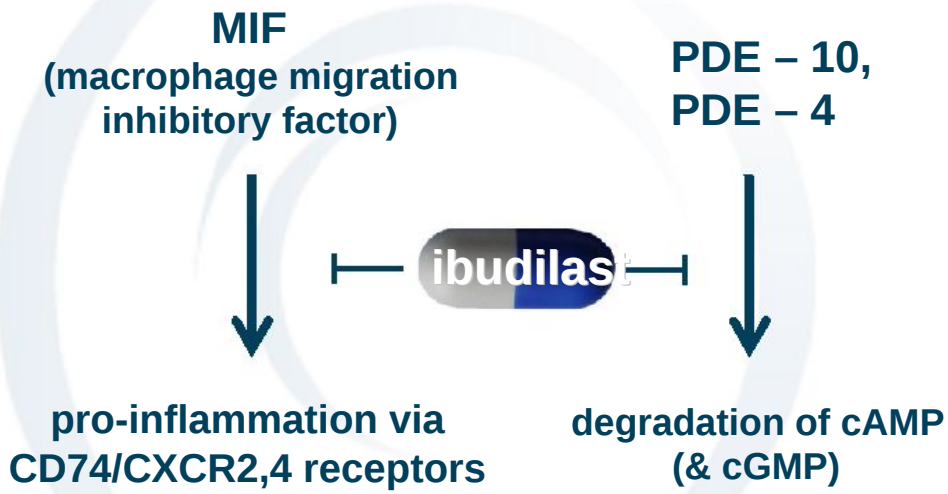
## MN-166 (ibudilast) Overview

---

- Non-addictive, orally-administered small molecule
  - NCE in U.S. and Europe: NCE exclusivity / Data exclusivity
- Large safety database with over 3.2M patient exposures in Japan
  - Primary use is in cerebrovascular disorders (post-stroke dizziness)
  - Pharmacokinetic (PK) enabled once or twice daily dosing
- Unique mechanism of action
- Encouraging Phase 1/2 data in targeted CNS indications with major unmet medical needs
- Received **Fast Track** designation from U.S. FDA for the treatment of methamphetamine addiction
- U.S. Patent protection until at least 2030 for addiction and 2029 for progressive multiple sclerosis (MS)



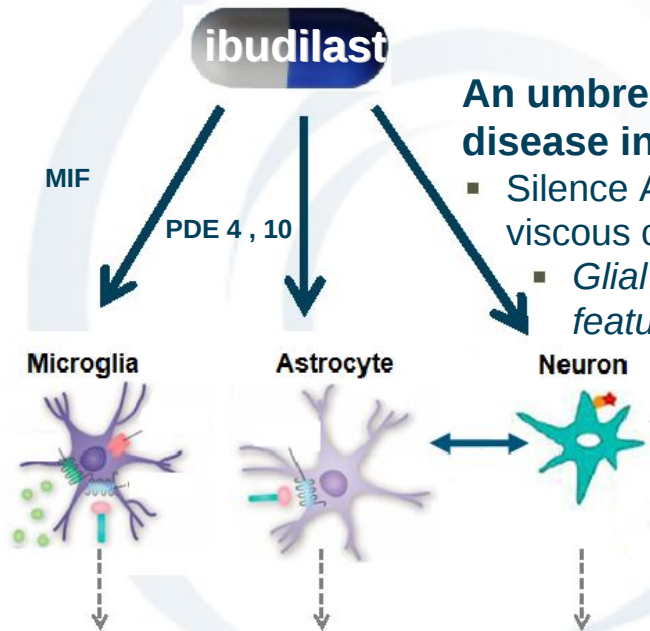
# MN-166 (ibudilast) Target Action - Molecular







# MN-166 (ibudilast) Target Action - Cellular



**An umbrella of cellular action covering the disease indications...**

- Silence Activated Glia & interrupt glial-neuronal viscous cycle
- *Glial cell activation is associated with key features of drug addiction*

**Withdrawal symptoms, drug-seeking and relapse associated with drug addiction; Neuropathology in drug addiction & progressive MS**



# MN-166 (ibudilast)-Methamphetamine (MA) Phase 1b Trial

## Trial Design

**n = 11**

Non-treatment seeking MA dependent subjects

Double-blind, placebo-controlled

~1 month inpatient hospitalization

Dosing:

One week each of Placebo, 40 mg/day, 100 mg/day

### Safety/Efficacy Measurements:

- Cardiovascular response to 15, 30 mg IV MA
- Cognitive & Subjective effects

## Partners

National Institutes of Health

**NIDA** NATIONAL INSTITUTE  
ON DRUG ABUSE  
*The Science of Drug Abuse & Addiction*



## Status: Completed

Data presented in June 2013 at CPDD\*

\*College of Problems of Drug Dependence



## MN-166 (ibudilast)-Methamphetamine Phase 1b Trial

---

✓ Data presented at Annual CPDD Meeting in June 2013

### **Safety:**

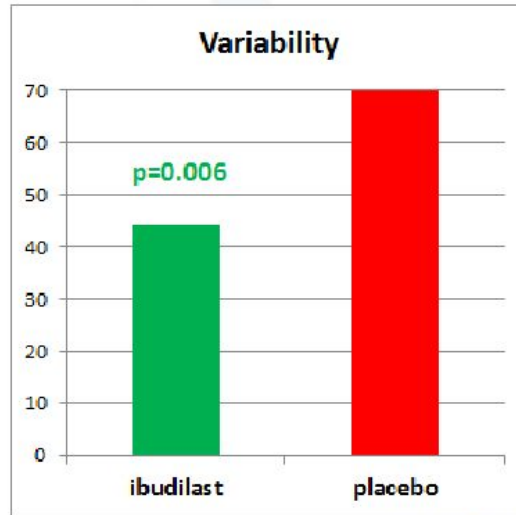
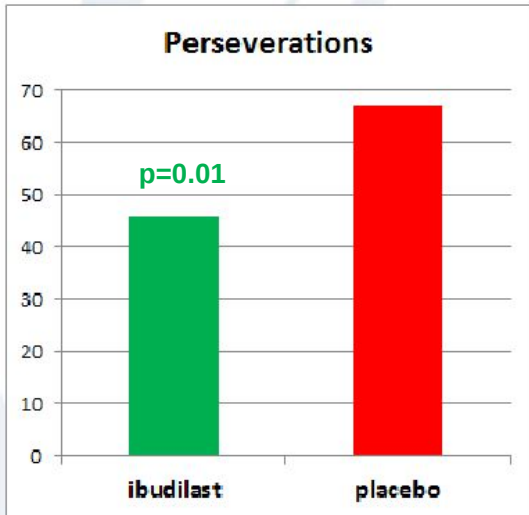
- Phase 1b trial established safety of co-administration of methamphetamine and MN-166 (ibudilast) in doses up to 100 mg/day
- Enables 100 mg/day dosing for Phase 2 outpatient trials



# MN-166 (ibudilast)-Methamphetamine Phase 1b Trial

## Efficacy:

- Conner's Continuous Performance Test-II (CPT-II) is a measure of sustained attention
- MN-166 (ibudilast) significantly reduced perseverations and variability in response times
- MN-166 (ibudilast) may have a protective effect on sustained attention



Note: Perseveration is a reaction time that is less than 100 ms; Variability is a measure of response speed consistency

MEDIGINOVA



# MN-166 (ibudilast) Phase 2 Trial for Methamphetamine Addiction

## Trial Design

**n = 140** (seek to increase to 160)

Treatment-seeking volunteers

Randomized, double-blind, placebo-controlled

1:1 Randomization with placebo or 100 mg/day of MN-166 (ibudilast)

12-week outpatient study

Primary endpoint is methamphetamine abstinence during final two weeks of treatment;  
✓ NIDA and FDA-preferred endpoint

## Partners



## Timing

Trial to commence 2H:2013



# MN-166 (ibudilast) Phase 1b/2a Trial: Opioid Withdrawal & Analgesia

## Trial Design

**n = 30**

Heroin-dependent subjects; 3-week inpatient setting

Double-blind, placebo-controlled

Week One:

All subjects on morphine (30 mg/day) and Placebo

Week Two:

All subjects on morphine (30 mg/day) and either Placebo, 40 mg/day, or 80 mg/day of MN-166 (ibudilast)

Week Three:

Subjects continue on either Placebo, 40 mg/day, or 80 mg/day of MN-166 (ibudilast) with morphine removed

**Objective** Safety/tolerability and preliminary efficacy for opiate withdrawal and analgesia

## Partners



## Status: Completed

Completed end 2010

Results were presented at AAN\* in March 2013

\*American Academy of Neurology

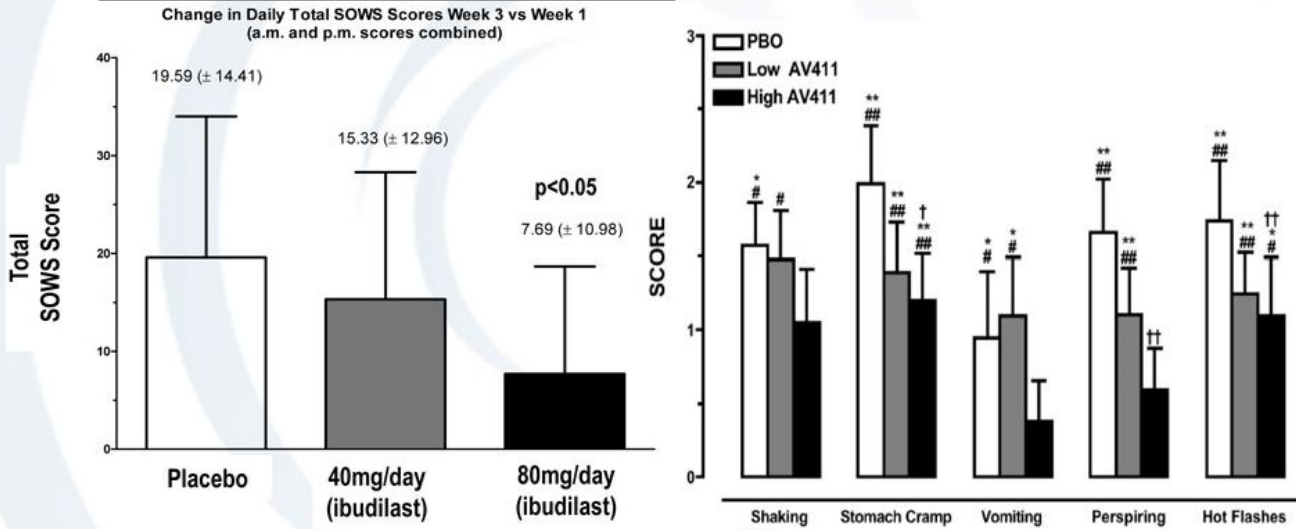


MEDICINOVA



# MN-166 (ibudilast) Phase 1b/2a Trial: Ibudilast Effect on Primary Outcome - Subjective Opioid Withdrawal Scale (SOWS)

Primary Endpoint = Total SOWS score as function of ibudilast dose  
as individual Measurements of SOWS Composite



Opioid-related pupil constriction was greater in the 80 mg/day ibudilast group compared to the placebo group ( $p \leq 0.05$ ) suggesting lessened tolerance development.

Note: One outlier subject in the 80 mg/day group was excluded from the Total SOWS score analysis.



# MN-166 (ibudilast) Phase 2a Trial: Effects of MN-166 (ibudilast) on Oxycodone Self-Administration in Opioid Abusers

## Trial Design

**n = 24**

Prescription opioid drug abusers (including OxyContin, Vicodin, Percocet) or heroin

Randomized, placebo-controlled, double-blind

Inpatient study; two 20-day cross-over periods in-clinic where patients detox & test self-administration when on Placebo or 100 mg/day of MN-166 (ibudilast)

**Objective** Assess effect of MN-166 (ibudilast) on craving and self-administration effects

## Partners



NEW YORK STATE

Psychiatric Institute

## Timing

Trial commenced at end of 2012

Trial completion expected 2H:2014





# Addiction Competitive Landscape

- No pharmaceutical treatment approved for methamphetamine addiction
- Available therapeutics for treating opioid addiction have limited efficacy and face increasing clinical-regulatory scrutiny
  - Buprenorphine & buprenorphine/naloxone combination (Subutex & Suboxone):
    - Potential for abuse, tolerance and addiction
    - Therapeutic effects reach a plateau at higher doses
    - Suboxone pills recently removed from shelves, highlighting the need for safer alternatives
  - Naltrexone:
    - Precipitates withdrawal symptoms resulting in poor patient compliance

MAJOR UNMET NEED FOR NOVEL TARGETS AND DIFFERENTIATED THERAPEUTICS



# US Methamphetamine Addiction Market

## US Market Opportunity of Methamphetamine Addiction

- ~353,000 individuals used methamphetamine in the past month
- ~70,600 patients seek treatment (20%)
- 6-month, initial course of treatment is recommended at ~\$1,000/month
  - $353,000 \times 0.20 \times \$1000/\text{month} \times 6 \text{ months} > \underline{\$400 \text{ million market}}$

(1) Dr. Phil Skolnick, Director, Division of Pharmacotherapy & Medical Consequences of Drug Abuse, NIDA 2010 NSDUHS Survey; Neuropsychiatric R&D Conference, San Francisco, September 2012



## US Market Opportunity for Opioid Addiction

- Current market for opioid addiction is well-established with *substitution therapeutic agents* such as Subutex/Suboxone with worldwide sales of ~\$1.3B<sup>(1)</sup> in 2012
- Approximately 1.4 million people with nonmedical pain reliever addiction and approximately 369,000 heroin addicts in the U.S.<sup>(2)</sup>
- A non-addictive treatment would fill an unmet need in this large market

(1) Reckitt Benckiser Annual Report, 2012; Assumed USD

(2) Substance Abuse and Mental Health Services Administration's (SAMHSA) 2011 National Survey on Drug Use and Health



**MN-166 (ibudilast):**  
**A Novel Oral Therapy**  
**for the Treatment of**  
**Progressive Multiple Sclerosis (MS)**



# MN-166 (ibudilast): The Promise in Progressive MS

---

- ✓ MN-166 (ibudilast) is a small molecule with established safety
- ✓ 297-patient, two-year Phase 2 clinical trial completed in MS
  - Significant dose-related improvements in disability progression and MRI outcomes (whole brain atrophy, black-hole formation)
  - Results indicated that MN-166 (ibudilast) is best suited to treat Progressive MS
- ✓ Glial-neuronal activation cycle leads to underlying progressive neurodegeneration
- ✓ MIF knock-out reduces the neuropathological and clinical disability sequelae in animal models
- ✓ Phase 2b development of MN-166 (ibudilast) for the treatment of Progressive MS via Academic Investigator/Government agency/MS society/MediciNova consortium(s) and grant funding



# MN-166 (ibudilast) Phase 2 Multiple Sclerosis Trial

## Trial Design

**n = 297**

Multi-arm Phase 2 randomized, double-blind trial

25 centers in Central & Eastern Europe

24-month study, with interim 12-month efficacy analyses

Dosing: 30 mg/day or 60 mg/day of MN-166 (ibudilast) or placebo

**Safety:** 83% completed the full 24 month study; AEs related to mild, self-limiting GI

### **Efficacy:**

- *Significant* attenuation of brain volume loss ( **$p=0.035$** )
- *Significant* attenuation of conversion of acute lesions to persistent black holes ( **$p=0.004$** )
- Sustained disability progression was *significantly* less likely ( **$p=0.026$** )
- *Significant* improvement in time to first relapse ( **$p=0.04$** )



# MN-166 (ibudilast) Phase 2 Multiple Sclerosis (MS) Trial

## Whole Brain Atrophy Endpoint in Secondary Progressive MS (SPMS) Patients

	Placebo	30 mg/day Low Dose Group		60 mg/day High Dose Group	
Patient Subset	% Brain Volume Change	% Brain Volume Change	Magnitude of Effect	% Brain Volume Change	Magnitude of Effect
RRMS	-1.2	-1.1	8% less	-0.8	<b>33% less**</b>
SPMS	-1.0	-0.7	30% less	-0.44	<b>56% less</b>

Mean change  
**\*\*p=0.035**

RRMS = Relapsing Remitting MS  
SPMS = Secondary Progressive MS



# MN-166 (ibudilast) Phase 2 Multiple Sclerosis (MS) Trial

## Whole Brain Atrophy Endpoint in Secondary Progressive MS (SPMS) Patients

Patient Subset	Placebo	30 mg/day Low Dose Group		60 mg/day High Dose Group	
	% Brain Volume Change	% Brain Volume Change	Magnitude of Effect	% Brain Volume Change	Magnitude of Effect
RRMS	-1.2	-1.1	8% less	-0.8	<b>33% less**</b>
SPMS	-1.0	-0.7	30% less	-0.44	<b>56% less</b>

**MediciNova is pursuing grant funding to support Phase 2b clinical trial(s) treating Progressive MS with MN-166 (ibudilast)**

Mean change  
\*\*p=0.035

RRMS = Relapsing Remitting MS  
SPMS = Secondary Progressive MS







# MN-166 (ibudilast) Clinical Trials

- MN-166 (ibudilast) is advancing in multiple Phase 2 programs

Indication	Preclinical	Phase 1	Phase 2	Phase 3
<b>Methamphetamine Dependence</b> UCLA, Funded by NIDA		Fast Track		
<b>Opioid Dependence</b> Columbia University, Funded by NIDA				
<b>Medication Overuse Headache (MOH)</b> University of Adelaide, Funded by Australian Gov't				
<b>Progressive Multiple Sclerosis</b> Pending Grant Funding				

GRANT-FUNDED CLINICAL DEVELOPMENT MODEL



# Key Milestones for 2013-2014

Clinical Milestones	Timing
✓ Results of Phase 1b UCLA methamphetamine trial	1H:2013
Commence Phase 2 UCLA methamphetamine trial	2H:2013
Announce grant funding for Phase 2b trial treating progressive MS with ibudiprat	2H:2013
Results of Phase 2a MOH pain trial	2H:2013
Results of Phase 2a opioid dependence trial	2H:2014

**MAJOR NEAR TERM VALUE INFLECTION POINTS**



# MN-166 (ibudilast) Program Patents



Patent	Exclusivity	Patent	Exclusivity
<b>Method of Use</b>		<b>Composition of Matter</b>	
<b>Addiction</b>	US Exp <sub>2</sub> 2030 EU Exp. 2026	<b>AV1013</b>	US Exp <sub>2</sub> 2027 EU Pending
<b>Progressive Multiple Sclerosis</b>	US Exp <sub>2</sub> 2029 EU Exp. 2028	<b>AV1013 Enantiomer</b>	US Exp <sub>2</sub> 2030 EU Pending
<b>Neuropathic Pain</b>	US Exp <sub>2</sub> 2025 EU Pending	<b>2<sup>nd</sup> Generation Analogs</b>	Pending
<b>Acute &amp; Sub-Chronic Pain</b>	US Pending EU Exp. 2028		
<b>Anxiety-Traumatic Brain Injury / PTSD</b>	Pending		
<b>Ibudilast + Immunomodulator for MS</b>	Pending		
<b>MOH Pain</b>	Pending		

\* U.S. patent expiration does not include Waxman-Hatch patent term restoration (industry average = 4.5 years)  
 © MedicInova, Inc. 2013





# Management Team with Global Experience

	Leadership	Years Experience	Background
	<b>Yuichi Iwaki, MD, PhD</b> President & CEO, Founder	36	Professor at USC, formerly Professor at University of Pittsburgh; Advisor to JAFCO, Tanabe
	<b>Michael Coffee</b> Chief Business Officer	28	Avigen, Amarin Corp., Elan Pharmaceuticals, N.A., Athena Neurosciences
	<b>Kirk Johnson, PhD</b> Chief Scientific Officer	23	Avigen, Genesoft Pharmaceuticals, Chiron Corporation (Novartis San Francisco)
	<b>Kazuko Matsuda, MD, PhD, MPH</b> Chief Medical Officer	22	Assistant Professor USC, Keck School of Medicine; Children's Hospital Los Angeles
	<b>Masatsune Okajima, CMA</b> VP, Head of Japanese Office	21	Daiwa Securities SMBC, Sumitomo Capital Securities, Sumitomo Bank
	<b>Michael Gennaro, CPA, MBA</b> Chief Financial Officer	38	Partner at FLG Partners, Sylanro Systems, Inverse Network Technology, Novell, Piiceon, Verticom