

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): February 15, 2012

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.)

4350 LA JOLLA VILLAGE DRIVE,
SUITE 950, SAN DIEGO, CA
(Address of principal executive offices)

92122
(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 February 15, 2012, 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 hereto 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 Coffee
Michael Coffee
Chief Business Officer

Date: February 15, 2012

EXHIBIT INDEX

Exhibit
No.

Description

99.1

Slide presentation of the Company.



*Accelerating
the global development
and commercialization of
innovative pharmaceuticals*



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 "believes," "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 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, MediciNova's ability to integrate its two ibudilast development programs and to pursue discussions with potential partners to secure a strategic collaboration to advance the clinical development of the combined development program, the availability of funds to complete product development plans and MediciNova's ability to raise sufficient capital when needed, or at all, MediciNova's ability to comply with the covenants in its financing agreements, intellectual property protection, 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, 2010 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 February 14, 2012. MediciNova disclaims any intent or obligation to revise or update these forward-looking statements.



Corporate Overview: MediciNova, Inc.

MediciNova Overview:

- Founded in September 2000
- Headquartered in San Diego, CA, with an additional office in Tokyo, Japan
- Dual listing on NasdaqGM as **MNOV** Osaka Securities Exchange as **4875**
- \$39.2 million market cap (NasdaqGM) as of 2/14/2012 (aggregate value of 18.3 million shares outstanding of common + preferred on an as converted basis)

In-Licensed Clinical Stage Compounds:

- Unique access to differentiated, potentially high-value assets primarily from Japanese alliances (Kissei, Kyorin, Mitsubishi Tanabe Pharma, Meiji)

New Approaches to Treat Serious Medical Conditions:

- Bedoradrine Sulfate (**MN-221**): Intravenous treatment for exacerbations of asthma and chronic obstructive pulmonary disease (COPD)
- Ibudilast (**MN-166/AV411**): Oral treatment for progressive multiple sclerosis, neuropathic pain, and drug addiction



Business Model: Return On Investment

In-License:

- Novel, small-molecule product candidates with significant clinical or preclinical data packages and attractive market opportunities

Conduct Proof-of-Concept Clinical Trials:

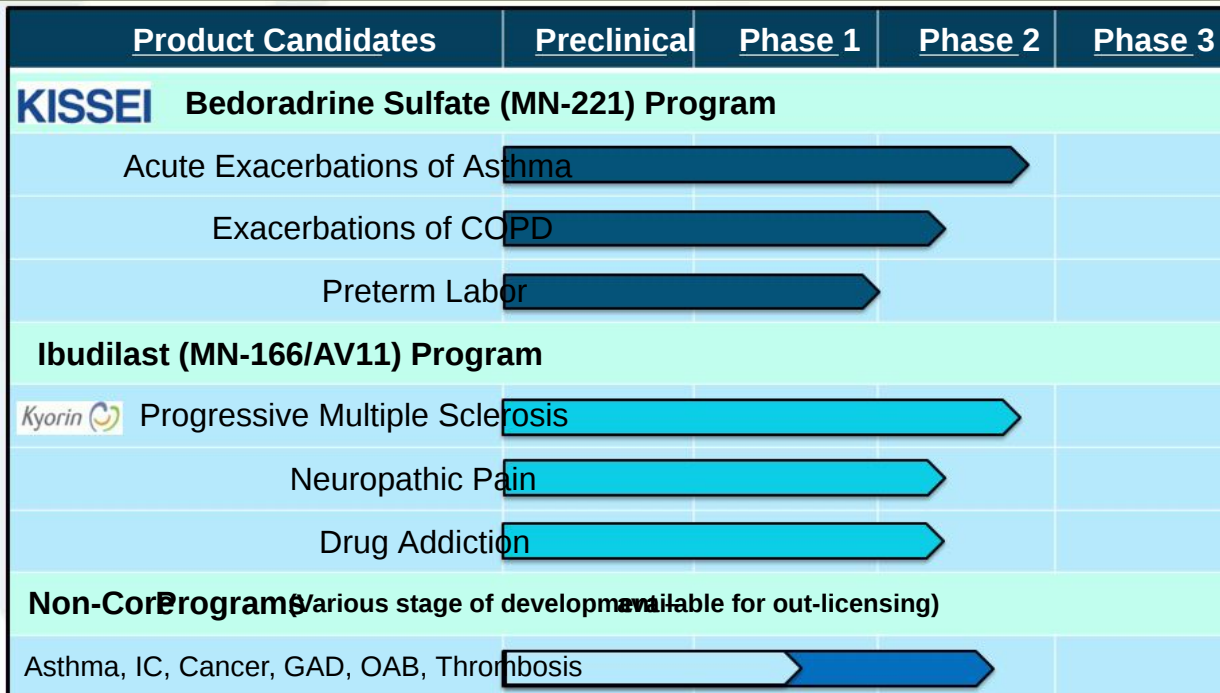
- Conduct Phase 1 and Phase 2 clinical trials to demonstrate safety and efficacy of compound

Two Pathways After Phase 2 (Proof-of-Concept):

1. Internal development of compound towards commercialization in North America
2. Seek partnership for further development of compound ex U.S.



Commercially-Attractive Diversified Portfolio





Significant Milestones

Milestone:

Timeline*:

- | | | |
|-------------------------------------|--|------------|
| <input checked="" type="checkbox"/> | Complete an Equity Raise (\$~7.9M net) | 1Q, 2011 |
| <input checked="" type="checkbox"/> | Commence Enrollment in Phase 1 Ibudilast trial for Meth. add | 2Q, 2011 |
| <input checked="" type="checkbox"/> | Sign Chinese Joint-Venture for MN-221 | 2Q, 2011 |
| <input checked="" type="checkbox"/> | Commence Enrollment in Phase 2 Ibudilast trial for MOH Pain | 3Q, 2011 |
| <input checked="" type="checkbox"/> | Complete Equity Raise and Funding from Kissei (\$10M) | 4Q, 2011 |
| <input type="checkbox"/> | Top-line Results from Phase 2b MN-221 CL-007 Acute Asthma Trial | 1Q, 2012 |
| <input type="checkbox"/> | Top-line Results from Phase 1b Multi-Dose Trial in COPD | 2Q, 2012 |
| <input type="checkbox"/> | Plan to Initiate Phase 2b Clinical Program for Ibudilast (MS / Pain) | 2H, 2012** |

**Anticipated completion dates based on current projections*

***Tentative based on availability of non-dilutive financing*

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MN-221:

- ***Acute Exacerbations of Asthma***
- ***Exacerbations of COPD***



Acute Exacerbations of Asthma (AEA)

Definition:

- Long-lasting and severe asthma episode that is not responsive to initial bronchodilator or corticosteroid therapy

Market Opportunity*:

- Approximately 1.9 million annual emergency room visits in the U.S.
 - ~500,000 annual hospitalizations in U.S. (~560,000 in UK/Spain/Germany/France/Italy)
 - Average length of stay for asthma hospitalization is 3.3 days
 - Average cost for asthma hospitalization is \$6,477

Current Standard of Care (SOC):

- Inhaled beta agonists, inhaled anticholinergics, and IV or oral corticosteroids
- Current treatments are limited by **Bronchoconstriction** (insufficient airflow due to inflammation and airway constriction prevents inhaled drug uptake in the lungs) and **Mucus Plug Formation** (Persistent airflow limitation due to mucus secretion)

*Source: National Center for Health Statistics / CDC, WHO website, "Core Health indicators", 2007 National Hospital Discharge Survey, IMS Health's Disease and Condition Benchmarks – PharMetrics Integrated Database, 1/2007 – 12/2008
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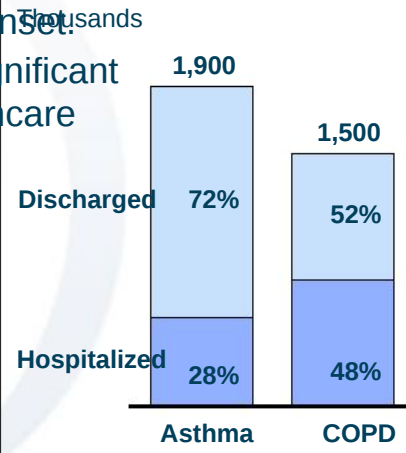
COPD Exacerbations

A COPD exacerbation is a sustained worsening of the patient's condition, from the stable state and beyond normal day-to-day variations, that is acute in onset.

COPD exacerbations are associated with a significant increase in mortality, hospitalization and healthcare utilization.

- 1.5 million hospital emergency department visits
- 765,000 hospitalizations
 - Average length of stay 7.4 days*
 - Average cost ~\$32,000*
- 119,000 deaths

Hospitalization rates amongst Asthma and COPD patients



COPD patients are generally more ill than asthmatics with overall higher hospitalizations and mortality.

Source: CDC, CDC COPD surveillance in U.S. 2000; US Census; American Lung Association website
*For COPD pts. with anemia; for pts. w/o anemia the stay is ~5.8 days at a cost of ~\$25K
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MN-221: A New Approach to Treating Acute Exacerbations (Asthma & COPD)

MN-221: A novel, highly selective β_2 adrenergic receptor agonist

Potential advantages over current therapy:

1. Improved Efficacy

- Route of administration (IV vs. inhalation)

2. Improved Safety

- High selectivity for β_2 receptor versus β_1
- Partial agonist for β_1 receptor*

3. Reduced Health Care Expenses

- Reduction in hospitalizations

* β_1 receptors are primarily responsible for cardiovascular stimulation



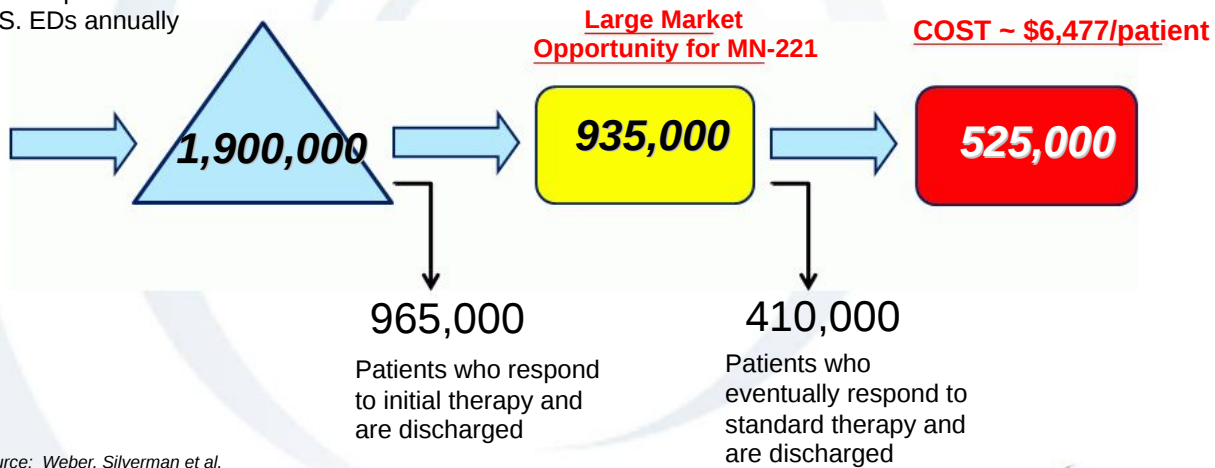
Acute Asthma Treatment Flow in Emergency Departments (EDs) in the U.S.

Input:
1,900,000 patients with acute exacerbations of asthma present at U.S. EDs annually

1st line therapy in ED:
Patients receive SOC, many while in the waiting room

2nd line therapy in ED:
Patients who do not initially respond continue receiving SOC

Hospitalization:
Patients who do not respond to SOC are eventually hospitalized



*Source: Weber, Silverman et al, American Journal of Medicine, 2002, Volume 113; pp 371

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MN-221-CL-007: Ongoing Phase 2b Trial

- Randomized, placebo-controlled, double-blind, multi-center Phase 2 clinical trial
 - Up to 170200 patients with severe, acute exacerbations of asthma ($FEV_1 \leq 50\%$ predicted) at multiple US emergency department sites
 - Two treatment groups of up to 85-100 patients/group
 - 1,200 μ g infusion of MN-221 over 1hr (600 μ g in first 15 minutes followed by 600 μ g in next 45 minutes) + Standard-of-Care
 - Standard-of-Care alone + placebo infusion
- **Enrollment almost complete; top-line results expected 1Q, 2012**



MN-221 CL-007 Efficacy Endpoints

MN-221 Asthma Clinical Endpoints for CL-007 Phase 2b Trial

1

ΔFEV_1

Area Under the Curve (AUC) of the change from baseline in FEV_1 (% predicted) during the 3-hour Treatment Period

• The study is designed to have 80% power and a two sided α -level of 0.05

2

Reduction in Hospital Admissions

Clearly-recognized Clinical and Pharmacoeconomic Benefit

3

Improvement in Clinical Signs of Asthma

- Respiratory Rate
- Accessory Muscle Use
- Supplemental Oxygen Use



MN-221-CL-012: Ongoing Phase 1b Trial

- Randomized, placebo-controlled, double-blind, Phase 1b clinical trial
 - 20 stable moderate-to-severe COPD patients ($30\% \leq FEV_1 \leq 80\%$)
 - Two treatment groups
 - 1,200 μ g infusions of MN-221 every 12 hours (15 pts.) for 3 days
 - Placebo (5 pts.)
 - Primary objective is to determine the safety and tolerability of MN-221 compared to placebo when administered multiple times over several days in COPD patients who may also have **co-morbidities** and **concomitant medications** common in this population.
 - Secondary endpoint is to evaluate pharmacokinetics and preliminary efficacy of repeated administration of MN-221 in COPD patients
- **Top-line results expected 2Q, 2012**



MN-221 Clinical Development

Acute Asthma Program:

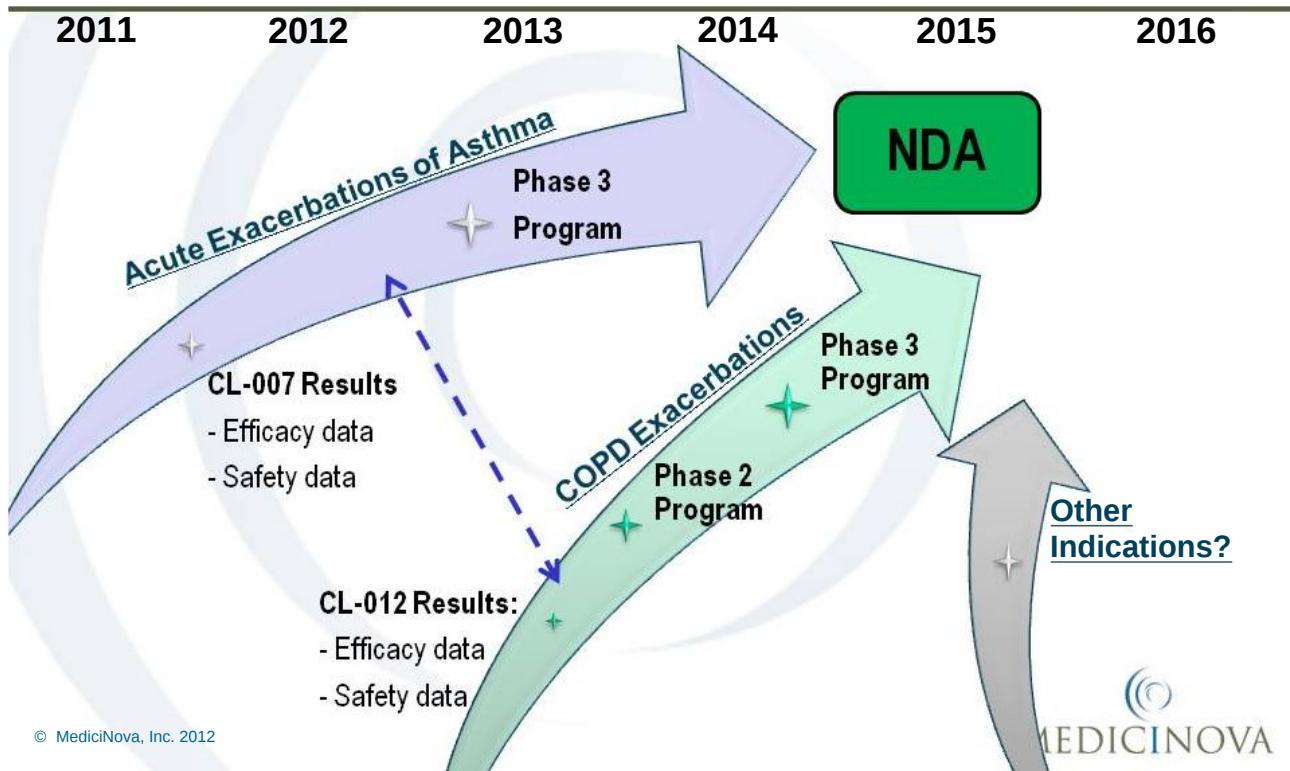
- Multiple doses tested at infusion lengths of 15min, 1hr, and 2hr
- Completed 2 trials in asthmatics with stable disease
 - **CL-004**(23patients)
 - **CL-005**(17patients)
- Completed Phase 2a trial in patients with AEA in the ED
 - **CL-006**(29patients)
- Ongoing Phase 2b proof-of-concept study in patients with AEA in ED
 - **CL-007**(~170-200pts.)
- Phase 3 trials N. & S. Hemispheres

COPD Program:

- Multiple doses tested at 1 hour infusion
- Completed 1 trial in COPD patients with stable disease
 - **CL-010**(48patients)
- Initiating screening in multi-dose trial in patients with stable COPD
 - **CL-012**(20patients)
- Efficacy and Safety data will also be very useful in further development of MN-221 for acute asthma



MN-221 Potential Development





MN-221:
Market Opportunity and
Patent Summary



MN-221 Market Opportunity*

Market	Acute Asthma	COPD Exacerbations
US	\$375-400 million	\$380-420 million
Europe	\$200-300 million	\$200-300 million
Rest of World	\$150-250 million	\$150-250 million
Worldwide MN-221 Sales Potential	\$725-950 million	\$730-970 million
Combined Worldwide MN-221 Sales Potential	\$1.5-1.9 Billion	

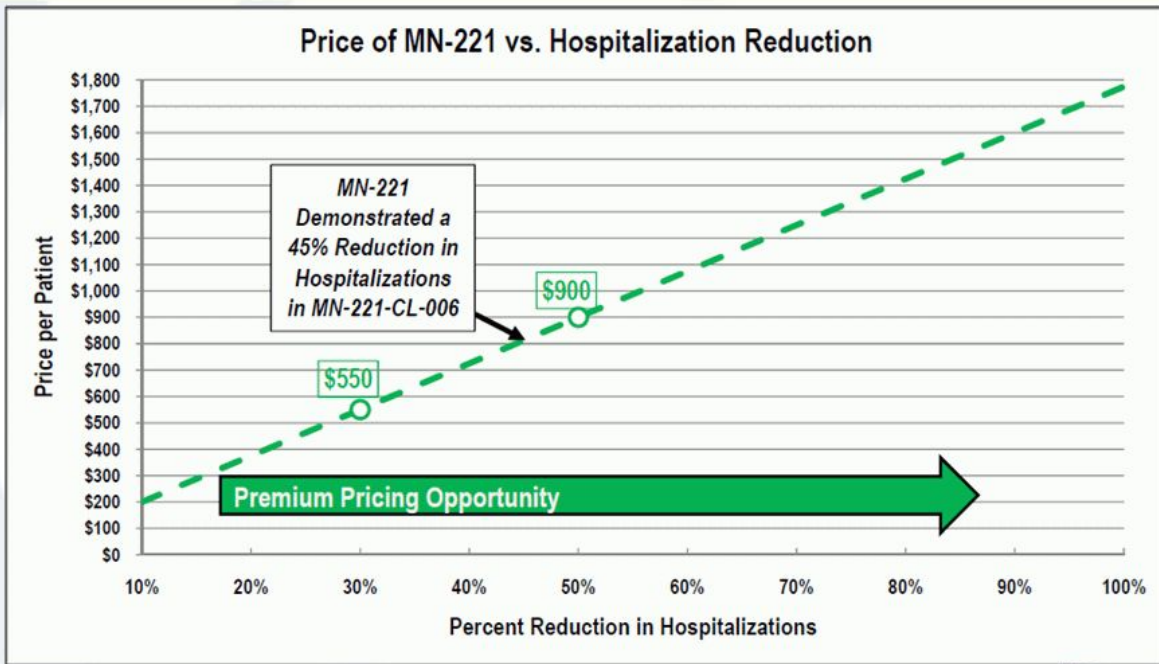
**Prices in today's dollars, do not reflect any price increases which may be implemented*

**Assumes a conservative price per dose target ~\$550/dose*

Source: Physician interviews, team analysis



Pharmacoeconomic Benefit: Price of MN-221 vs. % Hospitalizations



Source: Guidepoint Global survey of Medical Directors at U.S. managed care companies



MN-221 Patent Summary

- The U.S. patent for MN-221 has composition of matter and method of use claims and is set to expire no earlier than February 2017
 - Corresponding composition of matter patents in various other countries
 - U.S. patent expiration does not include Waxman-Hatch patent term restoration (industry average = 4.5 years)
 - Waxman-Hatch grants 5 years of exclusivity from approval in the U.S. (*We anticipate this along with pediatric exclusivity and ANDA review time will give us at least 7.0 years of exclusivity*)
- Exclusivity in Europe is 10 years for first approval of new chemical entities
- In addition, MediciNova has filed multiple patent applications related to MN-221 which if granted, could protect MN-221 until at least 2030

Ibudilast (MN-166/AV-411):

- ***Progressive Multiple Sclerosis***
- ***Neuropathic Pain***
- ***Addiction***



Ibudilast Overview

Ibudilast

- Oral administration
- Safe and well tolerated
 - Approved in Japan/Korea over 3.2M patient exposures
 - >420 subjects treated with ibudilast
 - Dosing up to 100 mg single dose
- Mechanism(s) of action primarily:
 - Inhibition of macrophage Migration Inhibitor Factor (MIF)
 - PDE-4,10 inhibition
 - Attenuation of glial cell activation

Clinical Safety & Preliminary Efficacy Established

- Phase 2 multiple sclerosis proof-of-concept study
 - Efficacy on disease progression endpoints validated at 60 mg/d
- Phase 1 dosing to 100 mg/d
- Phase 1b/2a trial in diabetic neuropathic pain
- Phase 1b/2a clinical trial in opioid withdrawal & analgesia



Ibutilast – Ongoing and Future Development

	1Q 2012	2Q 2012	3Q 2012	4Q 2012
Ibutilast (MN-166/AV11) Program				
Progressive MS* / Neuropathic Pain* Phase 2b Trial (POC)			*Pending Grant / Partner Funding	
Opioid Dependence Columbia University Phase 2a Trial				
Medication Overuse Headache Pain Univ. Adelaide Phase 2a Trial				
Methamphetamine Addiction UCLA Phase 1b Trial				



Strategy for Ibudilast's Development

- **Collaboration with Development Partner:**
 1. Advance to Phase 2b Proof-of-Concept in MS and/or Pain
 2. Provide competitive economics for first in class therapy
 3. Could be collaboration through:
 - i. Pharma partner
 - ii. Project financing
 - iii. Shared-risk with competitive CRO agreement
- **Sustain NIDA-sponsored Drug Addiction Development**
- **Potential for Gov't and MS Society consortium funding of Phase 2 POC Trial**
- **Consider Investigator-sponsored Neurological Trials**



Patent/Commercial Overview

Method of Use

MS Exp. 2018	Neuropathic Pain Exp. 2025	MIF Inh. screen Exp. 2027	Addiction Exp. 2026	Progressive M Exp. 2029
	Acute & Sub chronic Pain Exp. 2027	MOH Pain	Anxiety/Traumatic Brain Injury/PTSD	Ibudilast + Immunomodulator for MS

Composition of Matter

AV1013 Exp. 2027	2nd Generation Analogs
	AV1013 Enantiomer Exp. 2028



Key:

Issued or Allowed	Pending
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Management Team with Global Experience

	Leadership	Years Experience	Background
	Yuichi Iwaki, MD, PhD CEO & President	35	Professor at USC, formerly Professor at University of Pittsburgh; Advisor to JAFCO, Tanabe
	Michael Coffee Chief Business Officer	26	Avigen, Amarin Corp., Elan Pharmaceuticals, N.A., Athena Neurosciences
	Kirk Johnson, Ph.D. Chief Scientific Officer	21	Avigen, Genesoft Pharmaceuticals, Chiron Corporation (Novartis San Francisco)
	Masatsune Okajima, CMA VP, Head of Japanese Office	19	Daiwa Securities SMBC, Sumitomo Capital Securities, Sumitomo Bank
	Kazuko Matsuda, M.D., Ph.D., MPH Chief Medical Officer	20	Assistant Professor USC, Keck School of Medicine; Children's Hospital Los Angeles.
	Michael Gennaro, CPA, MBA Chief Financial Officer	37	Partner at FLG Partners, Sylanro Systems, Inverse Network Technology, Novell, Piiceon, Verticom



Financial Overview

Financial Resources:

- **\$8.7 million** cash & cash equivalents as of 9/30/2011
- **+\$10 million** raised through equity sale and non-dilutive funding by Kissei in 4Q, 2011
 - \$7.5 million raised in private stock sale to Kissei Pharmaceutical Co., Ltd.
 - Kissei purchased 800,000 shares common stock at \$2.50/share
 - Kissei purchased 220,000 shares Series B preferred stock at \$25.00/share (convertible to common at 1:10 ratio)
 - \$2.5 million additional payment from Kissei
 - MediciNova to expand MN-221 program in asthma and COPD
- ~18.3 million shares outstanding of common + preferred on an as converted basis
- Cash Runway into 2013



MediciNova Corporate Summary

**Experienced
Management Team**

- ❖ Clinical development expertise
- ❖ Strong international presence, especially Japan
- ❖ Large and small pharma/biotech experience

**Well
Capitalized**

- Raised ~\$18M in 2011
- Cash Runway into 2013

**Upcoming
Milestones**

1. Top-Line Results from CL-007 Trial
2. Top-Line Results from CL-012 Trial
3. Announce Plan for Ibudilast

**Anticipated completion dates based on current projections*

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Addendum

Data from Completed Trials

- ***MN-221***
- ***Ibudilast (MN-166/AV411)***

MN-221:

Data from Completed Trials

- Asthma Program:***

- CL-004, CL-005, CL-006***

- COPD Program:***

- CL-010***

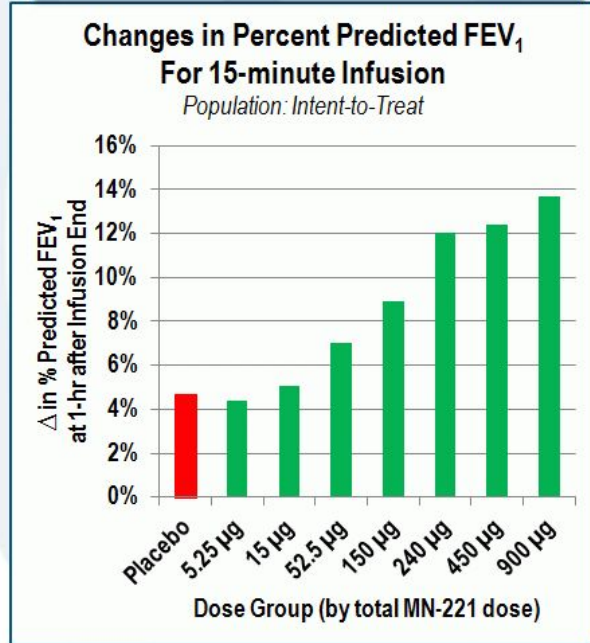
- Safety Review***



MN-221 Clinical Results

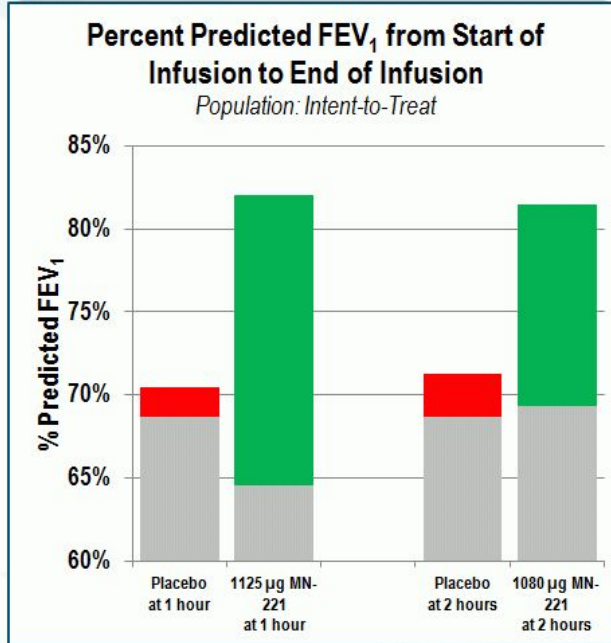
Improved Lung Function at Different Dosing Levels: Stable Asthmatics

CL-004: Stable Mild/Moderate Asthmatics



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CL-005: Stable Moderate/Severe Asthmatics



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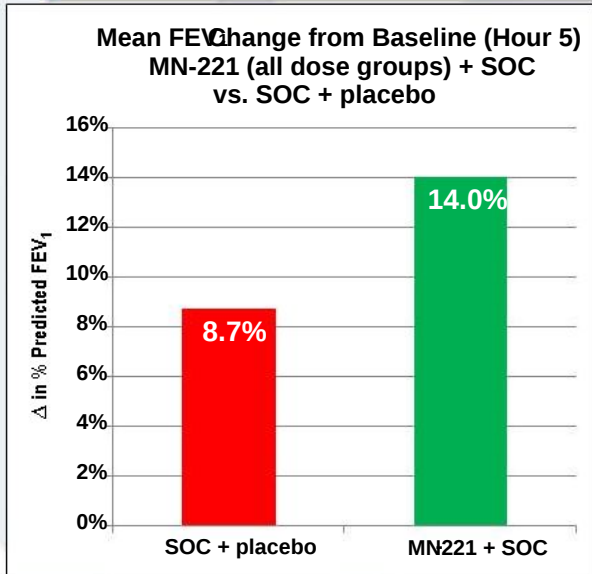
MEDICINOVA



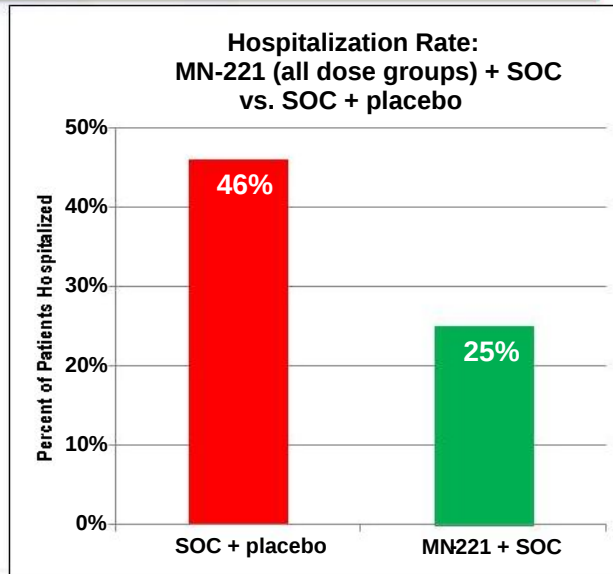
MN-221 Clinical Results

Improved Lung Function and Clinical Outcome Above and Beyond Standard of Care (SOC)

CL-006: Patients Suffering from Acute Exacerbation of Asthma in Emergency Department



Mean change in FEV₁ from baseline was 5.3% higher in the MN-221 dose groups versus the placebo group



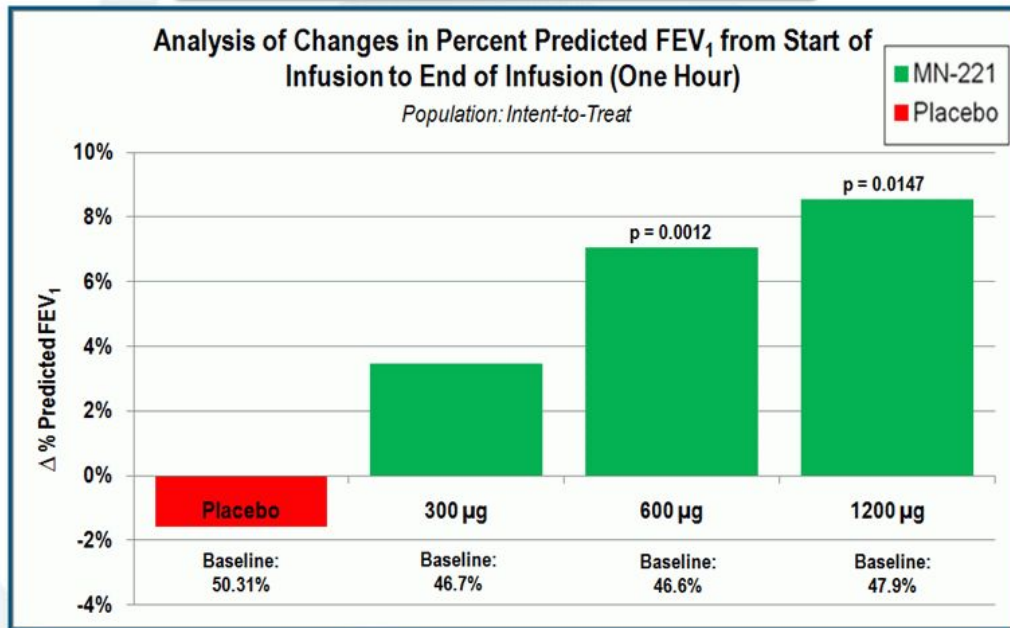
MN-221 reduced the hospitalization rate by 45%



MN-221 Clinical Results

Improved Lung Function at Different Dosing Levels: COPD Patients

CL-010: Stable Moderate/Severe COPD Patients





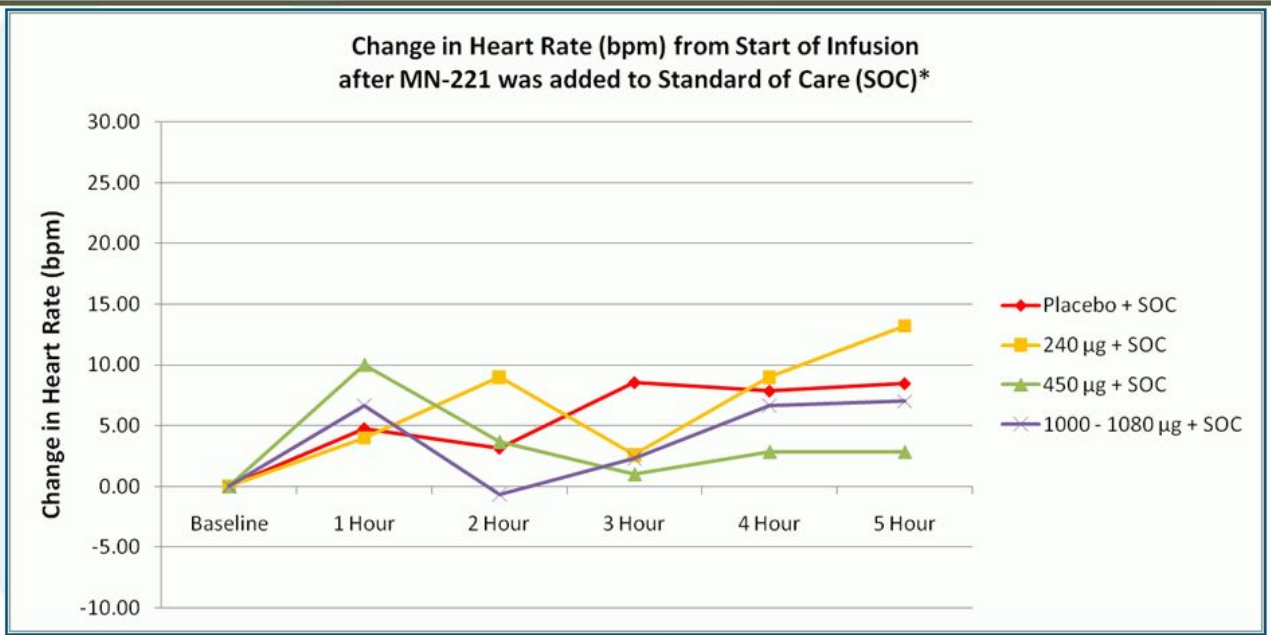
MN-221 Safety Review

- MediciNova has preclinical data and clinical data which demonstrates the safety of MN-221.
- In summary, we have not seen clinically significant safety concerns with MN-221 and it has been tested in ~300 subject to date.
- In the ongoing CL-007 trial our Data Safety Monitoring Board has reviewed safety data for 148 patients with no concerns for continued enrollment.
- According to interviews of emergency room physicians, less-selective injectable betaagonists such as epinephrine and terbutaline are not commonly used to treat acute asthma. The main reason they are not used more often is due to safety concerns, particularly cardiovascular side effects.



Safety Data: MN-221-CL-006

Mean Heart Rate - Change from Baseline



* All patients received Standard of Care including inhaled albuterol, inhaled ipratropium, and steroids.

Note: Baseline heart rate: 90 bpm for placebo, 95 bpm for 240µg, 103 bpm for 450µg, and 119 bpm for 1000-1080 µg

Source: Draft Clinical Study Report No. MN-221-CL-006



Human β -Adrenergic Receptor Selectivity

Test Drug	β_1 IC ₅₀ (M)	β_2 IC ₅₀ (M)	β_2 -Adrenoceptor Selectivity (IC ₅₀ for β_1 / IC ₅₀ for β_2)
Levalbuterol	7.40E-06	1.40E-06	5.3
Albuterol	9.40E-06	1.60E-06	5.9
Terbutaline	6.00E-05	6.50E-06	9.2
MN-221	5.90E-06	1.40E-07	42.4



MN-221: CHEST Posters (Nov. 2010)*

- **MN-221-CL-004** Evaluation of MN-221 (bedoradrine), Novel Highly Selective Beta2-Adrenergic Receptor Agonist in Mild to Moderate Asthma via Intravenous Infusion (Poster #145)
- **MN-221-CL-005** Comparison of Administration Rates of MN-221 (bedoradrine), Novel Highly Selective Beta2 Receptor Agonist in Patients with Stable Moderate to Severe Asthma (Poster #143)
- **MN-221-CL-006** Reduced Hospital Admission and Improved Pulmonary Function Following Intravenous MN-221 (bedoradrine), a Novel Highly Selective Beta2-Adrenergic Receptor Agonist, Adjunctive to Standard of Care in Severe Acute Exacerbation of Asthma (Poster #144)
- **Pharmacokinetic (PK) and Pharmacodynamic (PD) and Simulation Support the Novelty of MN-221**, a Highly-Selective Beta2-Adrenergic Agonist for Treatment of Acute Asthma (Poster #146)
- **MN-221 FY08-065** Cardiovascular Effects of i.v. MN-221 (bedoradrine) Administered with Nebulized Albuterol in Dogs (Poster #147)
- **Pharmacokinetics and Pharmacodynamics of MN-221**, Highly-Selective Beta2-Adrenergic Agonist for Treatment of Acute Chronic Obstructive Pulmonary Disease (Poster #685)
- **MN-221-CL-010** Intravenous MN-221, a Novel Highly Selective Beta2 Adrenergic Receptor Agonist, Improves Lung Function in Stable Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD) Patients (Poster #686)

*Posters available on MediciNova website at www.medicinova.com

Ibudilast (MN-166/AV411):

Data from Completed Trials

- ***Multiple Sclerosis Program***
- ***Neuropathic Pain Program***
- ***Drug Abuse/Addiction Program***
- ***Safety Review***



Multiple Sclerosis Clinical Study: MN-166-CL-001

Placebo-controlled, Randomized, Double-blind Phase II Study:

- Year 1 Placebo, 30 mg/day, 60mg/day
- Year 2 30 mg/day, 60mg/day
- 297 patients (~100 patients/group) @ 25 sites in Serbia, Ukraine, Belarus, Bulgaria and Romania

Key Inclusion Criteria:

- Males or females aged 18 to 55 years, with relapsing remitting (RR) and/or secondary progressive (SP) Multiple Sclerosis with continued relapses;
- One MRI scan taken two weeks prior to treatment start using a standardized MRI protocol with at least one Gd-enhancing lesion;
- An Expanded Disability Status Scale (EDSS) score of 5.5 or less at the screening and baseline visits.

Safety Profile:

- 89% (264 of 297) of subjects completed the first 12 months of the study
- 82.5% (245 of 297) of subjects completed the full 24 months of the study
- Adverse effects reported more frequently in MN-166-treated than placebo-treated subjects: GI effects & depression



MN-166-CL-001 Study Results

Indicative of Potential Neuroprotective Effect:

- Reduced brain volume loss **P-Value: 0.035**
- Reduced conversion of acute lesions to persistent black holes **P-Value: 0.004**
- Sustained disability progression was significantly less likely (~50%) **P-Value: 0.026**

Acute Clinical Benefit:

- Prolong time to relapse (by 127 days.) **P-Value: 0.04**
- Annualized relapse rate **P-Value: 0.08**

Protocol-Defined Primary Endpoint (Surrogate Endpoint):

- No significant reduction in the cumulative number of active (gadolinium-enhancing (T1) and non-enhancing new/enlarging (T2)) lesions on cranial MRI scans over 12 months of treatment was observed
- Positive trends were observed in volume of gadolinium-enhancing (T1) lesions **P-Value: 0.09**

Note: P-values listed on this slide compare placebo group to 60mg/day group of MN-166

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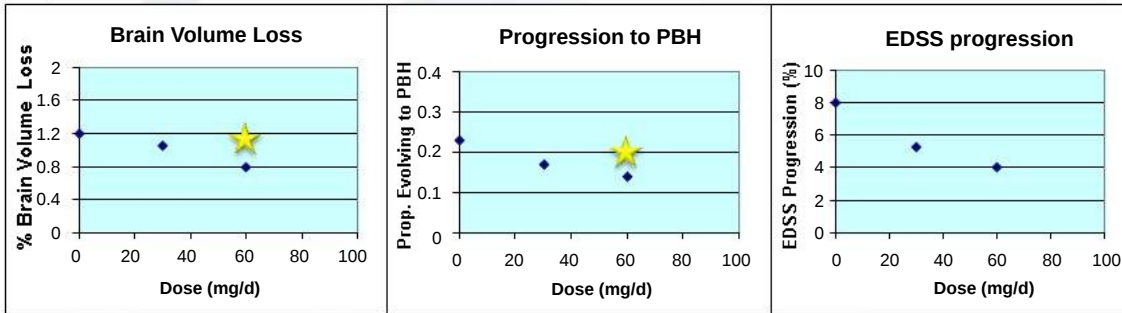
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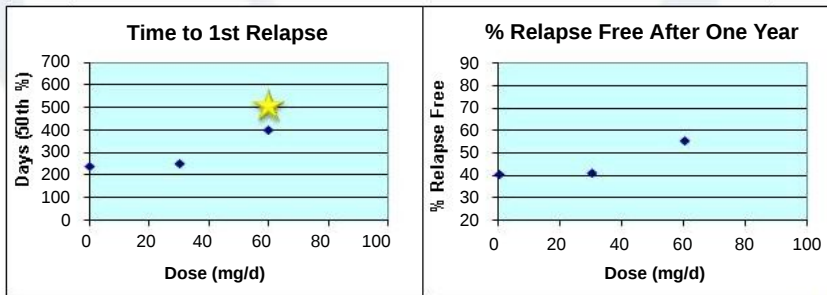


MN-166-CL-001: Efficacy Review (One Year)

Endpoints Indicative of Disease Modifying Effect (Chronic aspects of MS):



Endpoints Relating to Acute Clinical Benefit:



★ : Statistically significant



Secondary Progressive MS – Subset Analysis

Subset of MS Patients:	Treatment Group (patient n)				
	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 (81)	-1.1 (69)	8% less	-0.8 (75)	33% less
SPMS	-1.0 (3)	-0.7 (4)	30% less	-0.4 (2)	60% less

Next Steps for Progressive MS:

Two-year Phase 2 in Progressive MS - month 12 data. Potential first-in-class, once- or twice-daily oral well-tolerated drugs with established endpoints. Draft protocols, costs, and trial operations completed.



Diabetic Peripheral Neuropathic Pain Study: AV411-010

Design: Two-center (Australian), Phase 1b/2a, randomized, double-blind, placebo-controlled, parallel-group study.

Subjects:

- Patients, aged 18 to 75 years, with painful diabetic peripheral neuropathy (DPN) or complex regional pain syndrome (CRPS) of ≥ 6 months duration and screening VAS score on a 10 cm scale
- 29 subjects: 19 active, 10 placebo

Dosing:

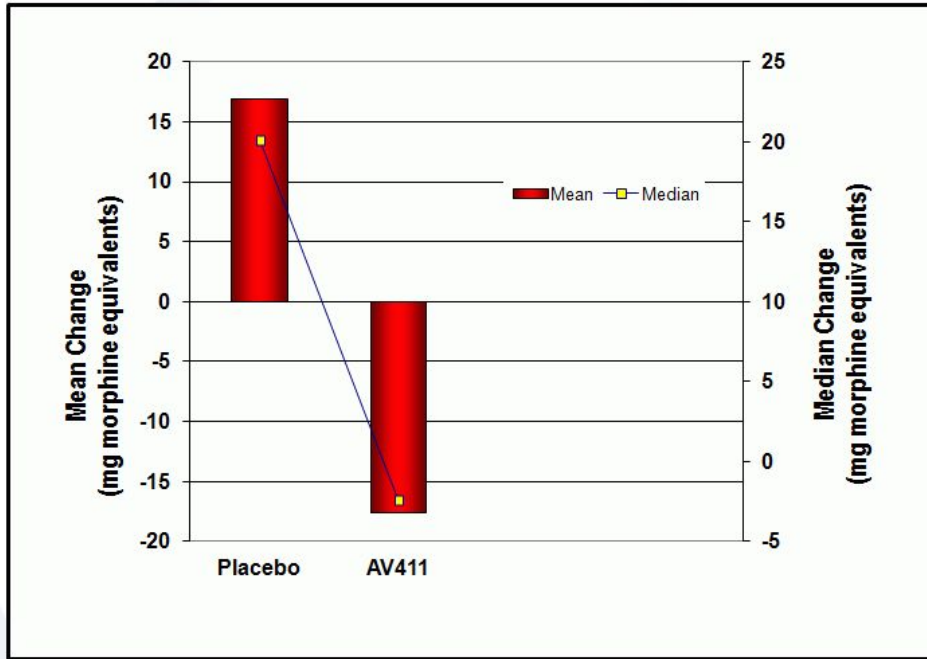
- 20 mg BID (n=4), 20 mg TID (n=4), 40 mg BID (n=11)
- AV411 added to patient standard medication regimen for DM and *pain*

Study objectives:

- Establish safety/tolerability & PK in intended patient population
- Explore potential efficacy endpoints



Reduction Observed in Opioid Usage





Greater % of “Responders” Above Ibudilast Plasma Thresholds

	Plasma Ibudilast Parameter	VAS ‘Responder’
AUG_{0-24h}	> 1000 ng*hr/mL	60%
	< 1000 ng*hr/mL	25%
C_{max}	> 60 ng/mL	64%
	< 60 ng/mL	14%
C_{min}	> 27 ng/mL	55%
	< 27 ng/mL	29%

Next Steps for Neuropathic Pain:

Twelve week Phase 2 DPN trial. Potential first-in-class once or twice daily, well-tolerated drug with established endpoints. Draft protocols, costs and trial operations completed.



Investigator-Led Development

- Recent validation of CNS action in opioid withdrawal & analgesia
- Ongoing Methamphetamine interaction Phase 1b
- Opioid self-administration Phase 2a initiating
- Ongoing Phase 2a Medication Overuse Headache Pain trial
 - Randomized, double-blind, placebo-controlled, investigator-initiated (Dr. Pail Rolan at Univ. of Adelaide, Australia; reduced headache index, acute medication (codeine) use and headache impact on Quality of Life (QOL); 8-week trial + follow-up; n = 20 patients each at placebo vs. 80 mg/day of MN-166
- Acquired rights to treatment of post-traumatic brain injury (TBI)
 - Led by the research of Daniel Barth, Ph.D., Professor of Neuroscience and Psychology at CU-Boulder, ibutilast demonstrated significant efficacy in a model of post-TBI anxiety, one of the most common disorders caused by TBI.



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