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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 25, 2015**

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**MEDICINOVA, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-33185**  
(Commission File  
Number)

**33-0927979**  
(IRS Employer  
Identification No.)

**4275 EXECUTIVE SQUARE, SUITE 650,  
LA JOLLA, CA 92037**  
(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)

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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 7.01 Regulation FD.**

On September 25, 2015, 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 furnished as Exhibit 99.1 and is incorporated herein by reference. The Company does not undertake to update this presentation.

*The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.*

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

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

**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.

**MEDICINOVA, INC.**

Dated: September 25, 2015

By: /s/ Yuichi Iwaki  
Yuichi Iwaki, M.D., Ph.D.  
President and Chief Executive Officer

EXHIBIT INDEX

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



**MNOV**  
**NASDAQ**  
LISTED  
**JASDAQ**  
証券コード：4875

*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 treatment 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 include without limitation statements regarding the future development and efficacy of MN-166, MN-221, MN-001 and MN-029. 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," "considering," "planning" 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, risks of obtaining future partner or grant funding for development of MN-166, MN-221, MN-001 and MN-029 and risks of raising sufficient capital when needed to fund MediciNova's operations and contributions 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, 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; 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 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 design or the execution of clinical trials, and the timing of expected filings with the regulatory authorities; 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 program and raise sufficient capital when needed, 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, 2014 and its subsequent periodic reports on Forms 10-Q and 8-K. Undue reliance should not be placed on these forward-looking statements, which speak only as of September 25, 2015. MediciNova disclaims any intent or obligation to revise or update these forward-looking statements.



# MediciNova Highlights

- **Novel product candidates** in clinical development with encouraging efficacy and safety data
  - **MN-166 (ibudilast)** for the treatment of Neurology Diseases including Progressive MS, ALS, and Drug Dependence
    - Approved in Japan in 1989 (post-stroke dizziness and asthma)
    - Large safety database
  - **MN-001** for the treatment of Fibrotic Diseases including NASH (nonalcoholic steatohepatitis) and IPF (idiopathic pulmonary fibrosis)
  - **MN-221** for the treatment of acute exacerbations of asthma
- **Well capitalized**
- **Experienced management team**



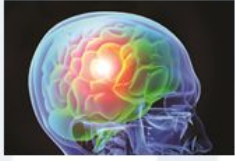
# MediciNova: Active Programs in Clinical Development

Core Programs / Indications	Preclinical	Phase 1	Phase 2	Phase 3
<b>MN-166, Oral Anti-inflammatory / Neuroprotective Therapeutic</b>				
<b>Neurodegenerative Diseases:</b>				
Progressive Multiple Sclerosis NeuroNEXT/Cleveland Clinic, <b>Funded by NINDS</b>		Fully Enrolled in Q2-2015		
ALS (Amyotrophic Lateral Sclerosis) Carolinas Neuromuscular/ALS-MDA Center				
<b>Drug Dependence:</b>				
Methamphetamine Dependence UCLA, <b>Funded by NIDA</b>		Fast Track		
Opioid Dependence Columbia University, <b>Funded by NIDA</b>				
Alcohol Dependence UCLA, <b>Funded by NIAAA</b>				
<b>MN-001, Oral Anti-inflammatory / Anti-Fibrotic</b>				
NASH (Nonalcoholic Steatohepatitis)		Fast Track	Pending (IND is Open)	
IPF (Idiopathic Pulmonary Fibrosis)	Orphan Drug	Fast Track	Pending (IND is Open)	
<b>MN-221, Intravenous Bronchodilator</b>				
Acute Exacerbations of Asthma				



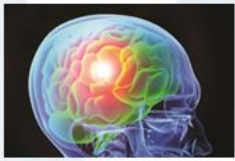


# Neurodegenerative Diseases



## Progressive Multiple Sclerosis "Progressive MS"

- MS affects more than 400,000 people in the U.S. and 2.3 million worldwide<sup>1</sup>
- Patients experience a diminished quality of life (e.g. fatigue, walking difficulties, weakness, pain, cognitive changes, depression)<sup>1</sup>
- **Market opportunity:** Total sales of RRMS drugs were \$18 billion worldwide in 2014. We believe Progressive MS market is at least as large as RRMS market.
- **Approved Drugs: NONE APPROVED for long-term treatment of Progressive MS**



## Amyotrophic Lateral Sclerosis (ALS) "Lou Gehrig's Disease"

- Fatal: ALS Life expectancy is 2-5 years<sup>2</sup>
- ALS affects up to 30,000 people in the U.S.<sup>2</sup> (Orphan indication)
- **Market opportunity:** an effective new drug for ALS could generate sales >\$1 billion per year<sup>3</sup>
- **Approved Drugs: RILUZOLE increases survival by only 2-3 months<sup>4</sup>**

1. Source: National Multiple Sclerosis Society
2. Source: ALS Association
3. Source: Cowen & Co. estimate
4. Cochrane Database of Systematic Reviews



# Fibrotic Diseases



## Nonalcoholic Steatohepatitis "NASH"

- NASH prevalence in the U.S. is 2-5%<sup>1</sup>
- Additional 10-20% have "fatty liver" due to being overweight or obese<sup>1</sup>
- NASH Market forecast: \$1.6 billion by 2020<sup>2</sup>
- **Approved Drugs: NO TREATMENT APPROVED**



## Idiopathic Pulmonary Fibrosis "IPF"

- IPF prevalence about 128,000 in the U.S.<sup>3</sup> (Orphan indication)
- Two-thirds of IPF patients die within 5 years<sup>3</sup>
- IPF Market forecast: >\$1 Billion in 2017<sup>4</sup>
- **Approved Drugs: Esbriet (pirfenidone) approved in October 2014; Esbriet Phase 3 studies enrolled mild to moderate IPF; No survival benefit shown**<sup>5</sup>
- **OFEV (nintedanib) approved in October 2014; Phase 3 studies enrolled mild to moderate IPF; No survival benefit shown**<sup>6</sup>

1. National Digestive Diseases Information Clearinghouse (NDDIC)
2. Allied Market Research
3. Coalition for Pulmonary Fibrosis
4. Research and Markets
5. Esbriet prescribing information
6. OFEV prescribing information

*Developing Novel Therapeutics...*

**MN-166**



**Ibudilast**

**MN-001**



**Tipelukast**

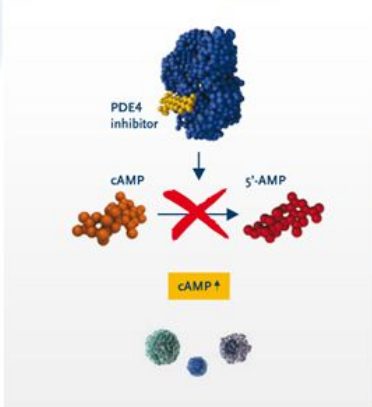


# How does MN-166 work?

MN-166



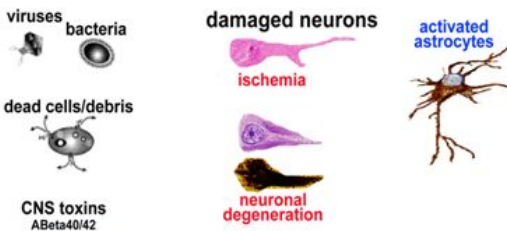
Ibudilast



## GLIAL CELL ATTENUATION

- **Role of Glia:**
  - Type of macrophage
  - Increases in number during brain damage
  - Glial activation leads to neurodegeneration
- **MIF Inhibition:**
  - Linked to attenuated disease progression in animal models of MS

### MICROGLIA STIMULATORS



## PDE inhibition

- Increases cAMP, reducing inflammation



# MN-166: MS Data

## MN-166 Phase 2 RRMS Data

- 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 ( $p=0.026$ )

## MN-166



## MN-166 Ongoing NIH-funded Phase 2b study

- PPMS and SPMS study
- Trial to be completed in 1H 2017



# MN-166: Addiction Data

MN-166



## MN-166 Opioid Withdrawal & Analgesia Phase 1b/2a Trial

- Reduce Subjective Opioid Withdrawal Scale (SOWS)
- Significantly reduced perspiring ( $p < 0.05$ ) and hot flashes ( $p < 0.05$ ), two components of SOWS

## MN-166 Opioid Self-Administration Phase 2a Trial (INTERIM DATA)

- Significantly decreased the craving for heroin ( $p < 0.05$ ), cocaine ( $p < 0.05$ ) and tobacco ( $p < 0.05$ )
- Significantly decreased the positive subjective effects of oxycodone measured by mean responses to statements such as “I Feel High” ( $p < 0.05$ ) and “I Liked the Dose” ( $p < 0.05$ )

## MN-166-Methamphetamine Phase 1b Trial

- Significantly reduced perseverations ( $p = 0.01$ ) and variability in response times ( $p = 0.006$ ), suggesting protective effects on sustained attention



# MN-166: Krabbe Disease

MN-166



## ~~FDA Grants Orphan Drug Designation to MN-166 for Krabbe Disease (June 2015)~~

- Krabbe disease is a rare genetic degenerative disorder for which there is no cure and is generally fatal before two years of age
- Only treatment option for Krabbe disease is hematopoietic stem cell transplantation, which has limited efficacy and potential risk to the patient

## **MediciNova has Open Investigational New Drug (IND) application with the Division of Neurology Products (DNP) for MN-166**

## **~~FDA Approval would generate valuable Priority Review Voucher~~**

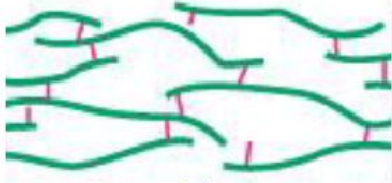
- Rare Pediatric Disease Priority Review Voucher can be sold
- BioMarin sold its voucher to Regeneron for \$67.5 million (July 2014)
- Retrophin sold its voucher to Sanofi for \$245 million (May 2015)
- United Therapeutics sold its voucher to AbbVie for \$350 million (August 2015)



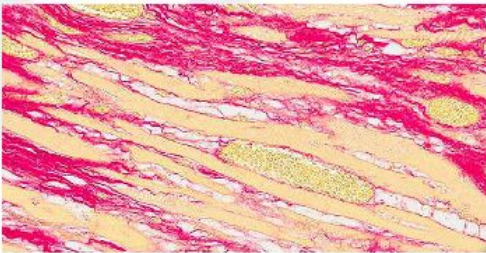
# What is Fibrosis?

## Fibrosis

Cross-linking of collagen and elastin



↓  
fibrosis

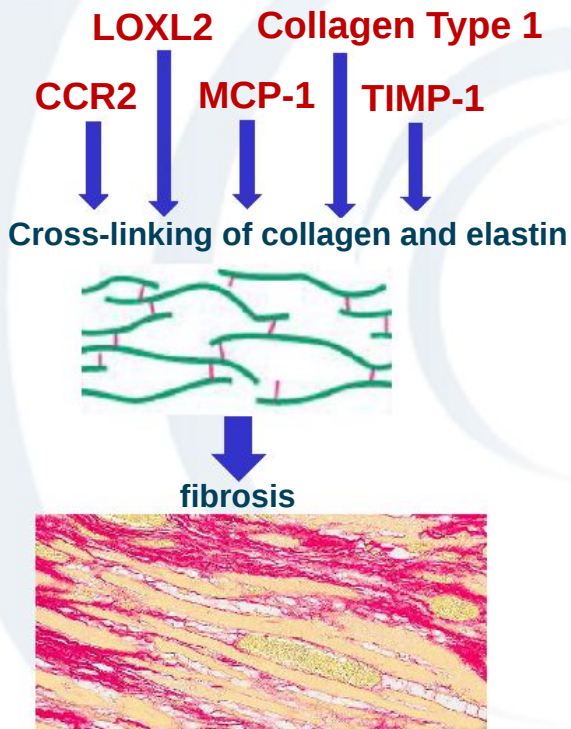


- Fibrosis is the development of excess fibrous connective tissue in an organ
- Fibrosis is a result of inflammation, irritation, or healing (e.g. scar)
- Cross-linking of collagen and elastin is the final step in fibrosis





# How does Fibrosis Develop?



## Genes Promoting Fibrosis

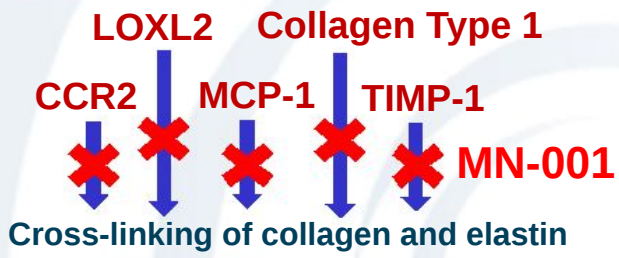
- LOXL2
- Collagen Type 1
- CCR2
- MCP-1
- TIMP-1



# How does MN-001 work?

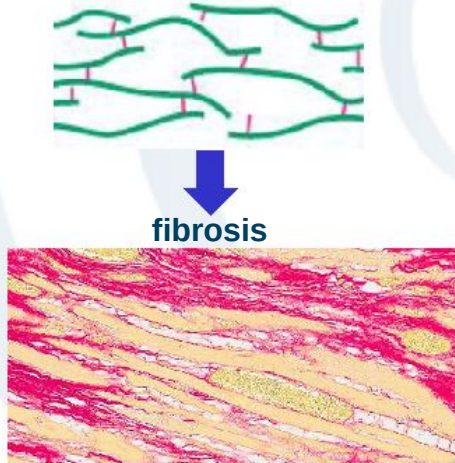
MN-001

Tipelukast



## MN-001 Reduces Gene Expression

- LOXL2
- Collagen Type 1
- CCR2
- MCP-1
- TIMP-1





# MN-001 Data

MN-001

Tipelukast



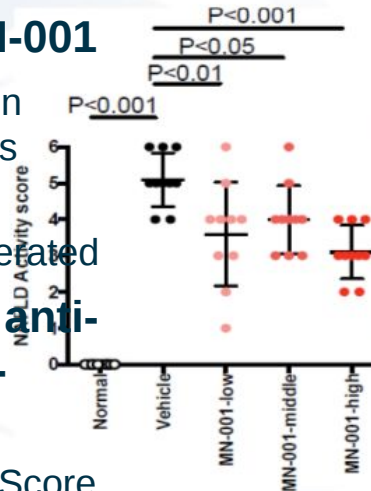
## More than 600 human subjects exposed to MN-001

- Phase 2 study of MN-001 in asthma with positive results
- MN-001 was considered generally safe and well-tolerated

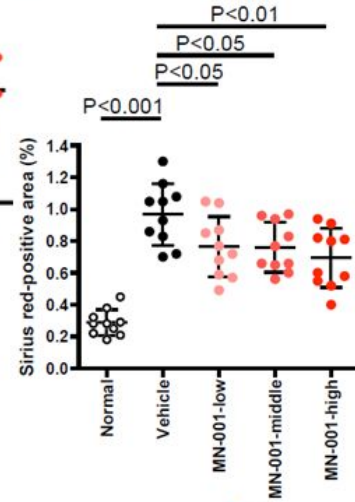
## Pre-clinical data shows anti-fibrotic effect in a Dose-Dependent Manner

- Improved NAFLD Activity Score (NAS) via a reduction in hepatocyte ballooning
- Reduced fibrosis area

NAFLD Activity Score (NAS)



% of fibrosis area

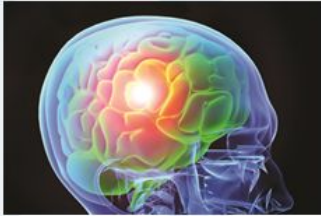




## Timeline - Progressive MS

**MN-166**

**Progressive  
Multiple Sclerosis  
“Progressive MS”**



- ✓ Q2 2013: Submit New IND Amendment and New Protocol
- ✓ Q3 2013: FDA Approval of Protocol & Study Initiation
- ✓ Q4 2013: Began Enrollment
- ✓ Q2 2015: Presentation at AAN
- ✓ Q2 2015: Completed Enrollment
- 2H 2016: Interim analysis
- 1H 2017: Final Results

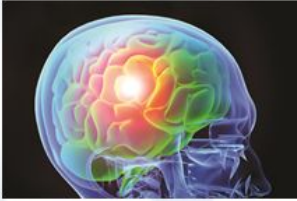




## Timeline - ALS

**MN-166**

Amyotrophic  
Lateral Sclerosis  
(ALS)  
"Lou Gehrig's  
Disease"



- ✓ Q3 2014: Submit New ALS Protocol as IND Amendment
- ✓ Q3 2014: FDA Approval to Start Study
- ✓ Q4 2014: Began Enrollment
- ✓ Q2 2015: Presentation at AAN: Positive Interim Safety Review
- ✓ Q3 2015: Amended Protocol to include 60 Advanced ALS patients using non-invasive ventilation (NIV)
- ☐ Q4 2015: Interim data



Carolinas HealthCare System



## Timeline - NASH

MN-001

Tipelukast

Nonalcoholic  
Steatohepatitis  
(NASH)



- ✓ Q1 2014: Positive preclinical data in NASH
- ✓ Q3 2014: Positive preclinical data in Advanced NASH
- ✓ Q4 2014: Present NASH data at AASLD and JDDW
- ✓ Q1 2015: Opened IND; FDA Approved Phase 2 Protocol
- ✓ Q1 2015: New Patent allowed for NASH
- ✓ Q2 2015: Fast Track designation granted
- ASAP: Initiate Phase 2 Study





## Timeline - IPF

MN-001

Idiopathic  
Pulmonary  
Fibrosis  
"IPF"



- ✓ Q2 2014: Positive preclinical data in pulmonary fibrosis
- ✓ Q3 2014: Present data at ICLAF
- ✓ Q4 2014: Prepare Protocol
- ✓ Q4 2014 FDA granted Orphan-drug designation to MN-001 for IPF
- ✓ Q1 2015: FDA Approved Phase 2 Protocol for moderate to severe IPF
- ✓ Q3 2015 FastTrack designation granted
- ASAP: Initiate Phase 2 Study

Tipelukast



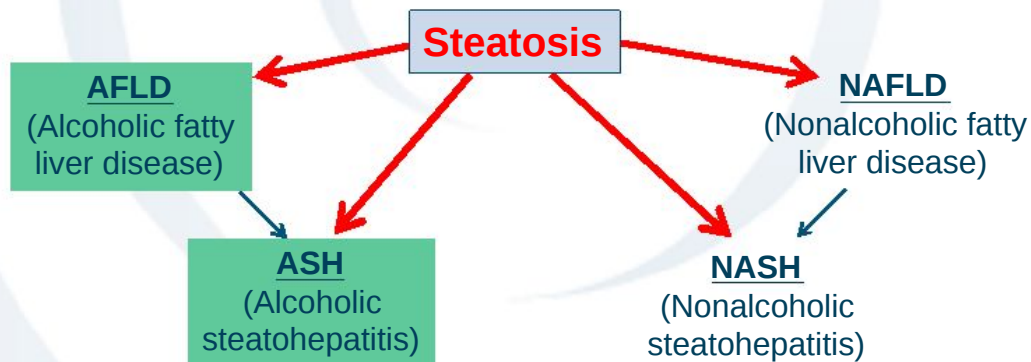


## MN-001 (tipelukast): 3 New Patents


**NASH:** New Patent covers MN-001 (tipelukast) and MN-002 (a major metabolite of MN-001) for treatment of nonalcoholic steatohepatitis (NASH); Expires no earlier than Dec 2032

**NAFLD:** New Patent covers MN-001 (tipelukast) and MN-002 (a major metabolite of MN-001) for treatment of nonalcoholic fatty liver disease (NAFLD); Expires no earlier than Dec 2032

**Liver Disorders:** New Patent covers MN-001 (tipelukast) and MN-002 (a major metabolite of MN-001) for the treatment of steatosis, lobular inflammation, hepatic ballooning, hepatic scarring, and elevated liver hydroxyproline levels; Expires no earlier than Dec 2032





<b>Timeline Summary</b>	<b>MN-166</b>  <b>Ibudilast</b>	<b>MN-001</b>  <b>Tipelukast</b>
<b>2014</b>	<ul style="list-style-type: none"> <li>ALS: New Protocol Submitted</li> <li>ALS: FDA Approval to Start Study</li> <li>ALS: Began Enrollment</li> </ul>	<ul style="list-style-type: none"> <li>NASH: Positive Preclinical Data</li> <li>NASH: Presented at AASLD and JDD</li> <li>IPF: Orphan Drug Designation Granted</li> <li>New Patents cover NAFLD, steatosis, and other liver disorders</li> </ul>
<b>2015</b>	<ul style="list-style-type: none"> <li>AAN Presentations for ALS and Progressive MS</li> <li>Progressive MS: Completed Enrollment</li> <li>ALS: Amended Protocol (Advanced ALS)</li> <li>ALS: Interim Data</li> </ul>	<ul style="list-style-type: none"> <li>NASH: Opened IND; Protocol Approved, New Patent covers NASH, Fast Track</li> <li>IPF: FDA Approved Protocol, Fast Track</li> <li>NASH: Announce Next Steps</li> <li>IPF: Announce Next Steps</li> </ul>
<b>2016</b>	<ul style="list-style-type: none"> <li>Progressive MS: Interim Analysis</li> </ul>	
<b>2017</b>	<ul style="list-style-type: none"> <li>Progressive MS: Final Results</li> </ul>	