MEDICINOVA INC
Form 424B5
August 21, 2012
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**Filed Pursuant to Rule 424(b)(5)**
**Registration No. 333-163116**

**PROSPECTUS SUPPLEMENT**

(to the Prospectus dated December 16, 2009)

# MEDICINOVA, INC.

## $20,600,000

## Common Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering up to $20,600,000 of our common stock, par value $0.001, to Aspire Capital Fund, LLC ( Aspire Capital ) under a Common Stock Purchase Agreement entered into on August 20, 2012.

The shares offered include (i) 363,636 shares of common stock to be issued to Aspire Capital in consideration for entering into the Common Stock Purchase Agreement, (ii) 606,060 shares of common stock that will be sold at a purchase price of $1,000,000 to Aspire Capital immediately upon execution of the Common Stock Purchase Agreement and (iii) additional shares of common stock with an aggregate offering price of up to $19,000,000 which may be sold from time to time to Aspire Capital until August 20, 2014. The purchase price for the additional shares of stock will be based upon one of two formulas, depending on the type of purchase notice we present to Aspire Capital. The purchase price for our stock sold pursuant to a regular purchase notice will be the lower of (i) the lowest sale price on the date of sale and (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days ending on the business day immediately preceding the date of sale. The purchase price for our stock sold pursuant to a volume-weighted average price purchase notice will be the lower of (i) the closing sale price on the date of sale and (ii) 95% of the volume-weighted average price for our common stock traded on the NASDAQ Global Market for the purchase date (or (a) if trading volume exceeds a certain limit as specified in the Common Stock Purchase Agreement or (b) if the sale price of the common stock falls below a certain threshold as specified in the Common Stock Purchase Agreement, the purchase price will be 95% of the volume-weighted average price for the trading volume up to such time).

Our common stock is listed on The NASDAQ Global Market under the symbol MNOV and on the Jasdaq market (formerly the Hercules Market until its closure in 2010) of the Osaka Securities Exchange under the code 4875. The last reported sale price of our common stock on The NASDAQ Global Market on August 20, 2012 was $1.88 per share.

**Before buying shares of our common stock, you should carefully consider the risk factors described in Risk Factors beginning on page S-6 of this prospectus supplement and page 3 of the accompanying prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement and the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of this prospectus supplement is August 20, 2012.**

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## ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. We urge you to carefully read this prospectus supplement and the accompanying prospectus, and the documents incorporated herein and therein, before buying any of the securities being offered under this prospectus supplement. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein.

You should rely only on the information contained in, or incorporated by reference into, this prospectus supplement and contained in, or incorporated by reference into, the accompanying prospectus. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement and the accompanying prospectus. You should not rely on any unauthorized information or representation. This prospectus supplement is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus supplement and the accompanying prospectus is accurate only as of the date on the front of the applicable document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus, or any sale of a security.

This prospectus supplement, the accompanying prospectus, and the information incorporated herein and therein by reference includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

All references in this prospectus supplement and the accompanying prospectus to MediciNova, the Company, we, us, our, or similar referenc refer to MediciNova, Inc. and its subsidiaries on a consolidated basis, except where the context otherwise requires or as otherwise indicated.

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## PROSPECTUS SUPPLEMENT SUMMARY

*This summary highlights selected information contained elsewhere in or incorporated by reference into this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our securities. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering. If you invest in our securities, you are assuming a high degree of risk. See Risk Factors.*

### About MediciNova, Inc.

**Our Business**

We are a development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs with a specific focus on the U.S. market. Through strategic alliances, primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates which we believe provide significant commercial opportunity for the Company. In December 2009 we acquired Avigen Inc., or Avigen, a biopharmaceutical company that focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential product candidate is a macrophage migration inhibitory and a glial attenuator for central nervous system, or CNS, disorders such as neuropathic pain, opioid addiction and withdrawal and methamphetamine addiction.

We believe that our ability to gain access to and acquire potentially high-value product candidates from Japanese and European pharmaceutical companies is largely attributable to the established relationships and broad industry experience of our management team. In particular, we believe our relationships with Japanese pharmaceutical companies and their executives provide us with a competitive advantage in opportunistically sourcing product candidates from Japanese pharmaceutical companies at attractive terms. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical Co., Ltd., or Kissei Pharmaceutical, Kyorin Pharmaceutical Co., Ltd., or Kyorin Pharmaceutical, Mitsubishi Tanabe Pharma Corporation and Meiji Seika Kaisha, Ltd., or Meiji Seika Kaisha, in Japan and Angiogene Pharmaceuticals, Ltd., or Angiogene Pharmaceuticals, in the United Kingdom, pursuant to which we have obtained rights to develop and commercialize our current product candidates.

Since our inception, we have acquired licenses to eight compounds for the development of ten product candidates which include clinical development for the treatment of acute exacerbations of asthma, multiple sclerosis (MS) and other central nervous system (CNS) disorders, bronchial asthma, interstitial cystitis (IC), solid tumor cancers, generalized anxiety disorders/insomnia, preterm labor and urinary incontinence. Two of such compounds have been in preclinical development for the treatment of thrombotic disorders. In addition, we have expanded our development program for MN-221 for the treatment of chronic obstructive pulmonary disease (COPD) exacerbations.

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At present, we are focusing our resources on the following prioritized product development programs:

| Product Candidate | Disease/Indication | Phase of Development | Licensor | Licensed Territory |
|---|---|---|---|---|
| MN-221 | Acute exacerbations of asthma and COPD exacerbations | Phase 2 clinical trial (CL-007) in emergency rooms to evaluate safety and efficacy in patients with acute exacerbations of asthma completed in the first quarter of 2012. On March 21, 2012 we announced completion of the 176 patient enrollment of the Phase 2 MN-221-CL-007 clinical trial. End-of-Phase 2 meeting pertaining to MN-221 for the treatment of acute exacerbations of asthma scheduled with the FDA on October 22, 2012. | Kissei Pharmaceutical | Worldwide, except Japan* |
| | | Phase 2 clinical trial in emergency rooms at planned escalating doses in patients with severe, acute exacerbations of asthma completed in Q2, 2009. | | |
| | | In the first quarter of 2012 we initiated an additional Phase 1b COPD clinical trial that has completed enrollment. Trial results are expected in the third quarter of 2012. | | |
| MN-166 | CNS disorders** | Phase 2 clinical trial in relapsing multiple sclerosis, or MS, completed in Q2, 2008. | Kyorin Pharmaceutical (MN-166) | Worldwide, except Japan, China, Taiwan and South Korea (MN-166) |
| | | Phase 1b/2a clinical trial in diabetic neuropathic pain completed in Q4, 2007. | | |
| | | Phase 1b National Institute on Drug Abuse, or NIDA, funded clinical trial in methamphetamine-dependent volunteers initiated in Q4, 2010. | | |
| | | Phase 1b/2a NIDA-funded clinical trial to evaluate safety and efficacy in heroin-dependent volunteers completed in Q4, 2010. | | |

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| | Investigator initiated Phase 2 clinical trial collaboration with a headache and pain specialist in Australia initiated in the third quarter of 2011. |

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* Pursuant to our license agreement with Kissei Pharmaceutical, Kissei Pharmaceutical has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties. We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. The joint venture agreement provides for the joint venture company to develop and commercialize MN-221 in China. A sublicense under which the joint venture company will license MN-221 from us will be required, which sublicense will require the consent of the licensor. We have not entered into the sublicense of MN-221 with the joint venture company as of the date of this prospectus supplement. There is no assurance the sublicense will be executed and there is no assurance that the joint venture company will be able to proceed with the development of MN-221 in China.

** Other CNS disorders encompass MS, neuropathic pain, opioid addiction and withdrawal and methamphetamine addiction. Upon completion of proof-of-concept Phase 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical or biotech companies to support further clinical development if we are unable to raise additional capital to conduct Phase 3 trials. Depending on the outcome of our End-of-Phase 2 meeting with the FDA in October 2012, relating to MN-221 for the treatment of acute exacerbations of asthma, and our ability to raise additional capital and/or to enter into a collaboration with a leading pharmaceutical or biotech company, we intend to define a Phase 3 trial and other development plans for MN-221 for the treatment of acute exacerbations of asthma and conduct one or more Phase 3 trials, and we intend to pursue the development of this drug candidate for the treatment of COPD. We also intend to enter into strategic alliances with leading pharmaceutical or biotech companies, industry consortia and/or research universities to support further clinical development of MN-166 for various CNS disorders, including progressive MS and drug addiction. We may also pursue potential partners and potential acquirers of license rights to our programs in markets outside the U.S. In addition, we continue to limit development activities for the balance of our existing product development programs in order to focus on our prioritized product development programs. For each of these remaining product candidates, we plan to conduct development activities only to the extent deemed necessary to maintain our license rights or maximize their value while pursuing a variety of initiatives to monetize such development programs. We cannot assure you that we will be successful in monetizing these programs on attractive terms, or at all. See *Risk Factors*.

**Company Information**

We were originally incorporated in the State of Delaware in September 2000. Our principal executive offices are located at 4350 La Jolla Village Drive, Suite 950, San Diego, CA 92122. Our telephone number is (858) 373-1500. Our website is www.medicinova.com, which includes links to reports we have filed with the Securities and Exchange Commission, or SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus supplement or the accompanying prospectus and should not be considered part of this prospectus supplement or the accompanying prospectus.

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**THE OFFERING**

| | |
|---|---|
| Common stock offered by us pursuant to this prospectus supplement | Shares having an aggregate offering price of up to $20.6 million. |
| Manner of offering | 363,636 shares will be issued to Aspire Capital in consideration for entering into the Purchase Agreement (defined below) (the Commitment Shares ), an initial sale of 606,060 shares with an offering price of $1,000,000 (the Initial Shares ), plus additional sales from time to time, subject to certain daily caps, of up to an aggregate offering price of $19,000,000 (the Purchase Shares ). See *The Aspire Transaction* on page S-36 and *Plan of Distribution* on page S-41. |
| Purchase Price of Shares | The purchase price for the initial sale of 606,060 shares to be completed immediately upon execution of the Purchase Agreement will be $1,000,000.<br><br>The purchase price for any subsequent sales of shares will be determined by formulas set forth in the Purchase Agreement on the purchase date for such shares, depending on the type of notice and the historical and current trading prices of our common stock on the NASDAQ Global Market. See *The Aspire Transaction* on page S-36 and *Plan of Distribution* on page S-41 |
| Use of proceeds | We intend to use the net proceeds from the sale of the securities under this prospectus supplement to fund our research and development efforts, and for general corporate purposes, including working capital and other general and administrative purposes. See *Use of Proceeds* on page S-33. |
| NASDAQ Global Market symbol | MNOV |
| Risk factors | This investment involves a high degree of risk. See *Risk Factors* beginning on page S-6 of this prospectus supplement as well as the other information included in or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should consider carefully before making an investment decision. |

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## RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks described below, together with the other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occur, our business, financial condition, results of operations or cash flows could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks described below and in the documents referenced above are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business operations.

### Risks Related to Our Business and Industry

***We have incurred significant operating losses since our inception and expect that we will incur continued losses for the foreseeable future.***

We are a development stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the quarter ended June 30, 2012, we had a net loss of $2.3 million and our accumulated deficit was $291.4 million. If we are successful in securing a strategic collaboration or in raising additional capital to support the expansion of our business, our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to the development of our product candidates.

If we have taxable income in the future, utilization of the net operating losses, or NOL, and tax credit carry-forwards will be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred. These ownership changes will limit the amount of NOL and tax credit carry-forwards that can be utilized to offset future taxable income and tax, respectively.

We believe that our working capital at June 30, 2012, will be sufficient to fund our operating requirements through at least March 31, 2013, assuming that we do not commence any new clinical trials and operate our business in accordance with our current operating plan. This belief is based on assumptions that could prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future cash requirements will also depend on many factors, including:

- progress in, and the costs of, future planned clinical trials and other research and development activities;
- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements, and to complete acquisitions of additional product candidates;
- the time and costs involved in obtaining regulatory approvals;
- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs associated with expanding our management, personnel, systems and facilities;

the costs associated with any litigation;

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- the costs associated with the operations or wind-down of any business it may acquire;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obtain regulatory approval to market our product candidates.

Based on our existing cash resources, we expect our research and development expenses to decline in 2012 relative to 2011 as we have completed our Phase 2 clinical trial of MN-221 for the treatment of acute exacerbations of asthma. If we are able to raise additional capital and/or enter into one or more strategic alliances, then we expect our research and development expenses to increase in connection with one or more clinical trials primarily related to MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, and any other development activities that we may initiate. In addition, our general and administrative expenses may increase in future periods as a result of several factors, including our research and development activities, our business development activities and any expansions in our infrastructure related to such activities. Our estimate of cash requirements for future operating expenses assumes that we do not commence a new clinical trial for MN-221 and that we do not fund any further significant clinical development of MN-166 unless we are able to raise additional capital and/or enter into one or more strategic alliances. We expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing drug products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

***If we fail to obtain the capital necessary to fund our operations, we will be unable to develop and commercialize our product candidates.***

We have consumed substantial amounts of capital since our inception. From our inception to June 30, 2012, we had an accumulated deficit of approximately $291.4 million. Our cash and cash equivalents were approximately $7.3 million at June 30, 2012.

Our business will continue to require us to incur substantial research and development expenses and we do not expect to be able to fund these expenses solely from upfront cash or milestones from collaborations or strategic alliances. As such we may be required to raise capital from one or more sources in the near term to continue our operations at or close to the levels currently conducted. We believe that without raising additional capital from accessible sources of financings, we will not otherwise have adequate funding to complete the development of MN-221 including pivotal clinical trials or the commercialization of any products we successfully develop. There is no guarantee that adequate funds will be available when needed from debt or equity financing, arrangements with partners, or from other sources, or on terms attractive to us. The inability to obtain sufficient additional funds when needed to fund our operations would require us to significantly delay, scale back, or eliminate some or all of our clinical or regulatory activities, further reduce general and administrative expenses and have a substantial negative effect on our results of operations and financial condition.

***We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.***

To date, we have funded our operations primarily from sales of our securities and, to a lesser extent, debt financing. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue if we can enter into collaborations, strategic alliances or other agreements that would provide us with such revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or

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with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve and maintain profitability.

***We are largely dependent on the success of our two prioritized product candidates, MN-221 and MN-166, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.***

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market any of our product candidates in the U.S. until we submit and receive approval of a New Drug Application, or NDA, for a product candidate from the FDA or its foreign equivalent from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations and MN-166, a combined ibudilast product development program covering MS and other CNS disorders, and the success of our business currently depends on their successful development and commercialization. Neither of these product candidates has completed the clinical development process; therefore, we have not submitted an NDA or foreign equivalent or received marketing approval for either of these two prioritized product candidates. In addition, we are not currently planning to fund any further significant clinical development of MN-166 until such time that we are able to secure a strategic collaboration to advance the combined development programs, which may delay or impede the process of completing clinical trials and seeking regulatory approval for this product candidate. We also cannot assure you that we will be able to secure such a strategic collaboration on attractive financial and other terms, or at all.

The clinical development programs for MN-221 and MN-166 may not lead to commercial products for a number of reasons, including our clinical trials failure to demonstrate to the FDA s satisfaction that these product candidates are safe and effective or our failure to obtain necessary approvals from the FDA or similar foreign regulatory authorities for any reason. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process or are unable to secure a strategic collaboration or partnership with a third party. Any failure or delay in completing clinical trials or obtaining regulatory approval for either MN-221 or MN-166 in a timely manner would have a material and adverse impact on our business and our stock price.

***If we are unsuccessful with our End-of-Phase 2 meeting with the FDA pertaining to the development of MN-221 for the treatment of acute exacerbations of asthma, we may be unable to develop and commercialize this product candidate.***

On May 23, 2012 we announced that preliminary trial results of the 176 patient enrollment of the Phase 2 MN-221-CL-007 clinical trial did not statistically meet the primary endpoint, improvement in FEV1 (Forced Expiratory Volume in One Second) compared to placebo. However, given the positive MN-221 efficacy and safety data displayed in this trial and other clinical trials of MN-221, we have scheduled an End-of-Phase 2 meeting with the FDA pertaining to the development of MN-221 for the treatment of acute exacerbations of asthma on October 22, 2012. An unsuccessful End-of-Phase 2 meeting with the FDA could significantly delay or materially and adversely impact our future development of MN-221, including the development and costs and timing for future trials and/or materially and adversely impact our ability to raise the capital necessary to advance development and fund our ongoing operations.

***We will rely on the joint venture company formed in China in 2011 to develop and commercialize MN-221 in China and there is no assurance that the joint venture will be able to successful in doing so.***

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. We have invested $680,000

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for 30% interest in the joint venture company. A sublicense under which the joint venture company will license MN-221 from us will be required, which sublicense will require the consent of the licensor. We have no assurances that the joint venture company will be successful in its efforts to conduct clinical trials necessary to gain regulatory approval of MN-221 or any other drug candidate pursued by the joint venture in China, will be able to successfully manufacture drug candidates for the Chinese market or will receive the future funding it will require to conduct operations. We have not entered into the sublicense of MN-221 with the joint venture company as of the date of this report. There is no assurance the sublicense will be executed and there is no assurance that the joint venture company will be able to proceed with the development of MN-221 in China or that we will someday recover our investment in the joint venture company.

***We may not realize all of the anticipated benefits of the combined clinical development programs based on ibudilast.***

We may not be able to successfully secure a strategic collaboration to advance the combined ibudilast development programs. Following completion of the Phase 2 clinical trial of MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of Avigen in December 2009, we have not undertaken, nor do we plan to undertake, any further significant clinical development of MN-166 until such time that we secure a strategic collaboration to advance the combined clinical development of MN-166 ibudilast-based development program. We cannot assure you that we will be able to secure such a strategic collaboration or otherwise further advance, or recognize value from, a combined MN-166 clinical development program.

***In order to commercialize a therapeutic drug successfully, a product candidate must receive regulatory approval after the successful completion of clinical trials, which are long, complex and costly, have a high risk of failure and can be delayed or terminated at any time.***

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. Clinical testing is expensive, takes many years and has an uncertain outcome. To date, we have obtained regulatory authorization to conduct clinical trials for eight of our product development programs. Investigational New Drug Applications, or INDs, were approved by the FDA and are active for seven of our product candidates. We also have obtained Clinical Trial Authorizations, or CTAs, for the MN-221-CL-007 Phase 2 clinical trial in Canada, Australia and New Zealand. Through the acquisition of Avigen, we have assumed responsibility for clinical trials including one active IND for neuropathic pain and cross-reference and drug product support of the NIDA-funded opioid withdrawal investigator-initiated IND with Columbia University drug addiction clinical researchers. In the third quarter of 2010, the FDA approved a NIDA-funded investigator-initiated IND with University of California Los Angeles to proceed with an initial trial of our neurological drug candidate, ibudilast (MN-166), as a potential new pharmacotherapy for methamphetamine addiction. The study is proceeding and in late 2011 collaborators and advocates of ibudilast utility in chronic pain initiated an Investigator-sponsored and funded phase 2 trial for ibudilast in a form of chronic headache pain related to opioid usage known as Medication Overuse Headache. MediciNova provides placebo and active drug product and safety and regulatory support.

It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any products derived from any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, in May, 2012, we announced the preliminary results from our Phase 2b clinical trial of MN-221 for patients with acute exacerbations asthma failed to statistically meet in its primary endpoint. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical

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trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after obtaining promising results in earlier clinical trials. In addition, any delays in completing clinical trials or the rejection of data from a clinical trial by a regulatory authority will result in increased development costs and could have a material adverse effect on the development of the impacted product candidate.

In connection with the conduct of clinical trials for each of our product candidates, we face many risks, including the risks that:

- the product candidate may not prove to be effective in treating the targeted indication;
- clinical trial participants and/or patients may experience serious adverse events or other undesirable drug-related side effects;
- the results may not confirm the positive results of earlier trials;
- the FDA or other regulatory authorities may not agree with our proposed development plans or accept the results of completed clinical trials; and
- our planned clinical trials and the data collected from such clinical trials may be deemed by the FDA or other regulatory authorities not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical trials or before the FDA will consider an application for marketing approval.

If we do not complete clinical development of our product candidates successfully, we will be unable to obtain regulatory approval to market products and generate revenues from such product candidates. We may also fail to obtain the necessary regulatory approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. In addition, even if we believe that the preclinical and clinical data are sufficient to support regulatory approval for a product candidate, the FDA and foreign regulatory authorities may not ultimately approve such product candidate for commercial sale in any jurisdiction, which would limit our ability to generate revenues and adversely affect our business. In addition, even if our product candidates receive regulatory approval, they remain subject to ongoing FDA regulations, including obligations to conduct additional clinical trials, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

***We are subject to stringent regulation of our product candidates, which could delay the development and commercialization of our product candidates.***

We, our third-party manufacturers, service providers, suppliers and partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. None of our product candidates can be marketed in the U.S. until it has been approved by the FDA. None of our product candidates has been approved by the FDA to date, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval for a product takes many years of clinical development and requires substantial resources. Additionally, changes in regulatory requirements and guidance may occur or new information regarding the product candidate or the target indication may emerge, and we may need to perform additional, unanticipated non-clinical or clinical testing of our product candidates or amend clinical trial protocols to reflect these changes. Any additional unanticipated testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce or negate our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements, including requirements related to testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA s requirements may change and additional

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government regulations may be promulgated that could affect us, our partners and our product candidates. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad.

In order to market any of our products outside of the U.S., we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods beyond the requirements of the FDA and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. Regulatory approval in one country, including FDA approval in the U.S, does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. A product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales, and any approval that we receive may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the U.S. or other countries, we may be subject to regulatory and other consequences, including fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

***Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.***

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, including additional research and development and clinical trials. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for MN-221 or MN-166, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the terms of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as commercial good manufacturing practices, or cGMPs, a regulatory agency may:

- issue warning letters or untitled letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;

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suspend regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products or require a product recall.

***If we fail to obtain and maintain approval from regulatory authorities in international markets for any of our current or future product candidates for which we have rights in international markets, our market opportunities will be limited and our business will be adversely impacted.***

Sales of our product candidates outside of the U.S. will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of our product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials. In many countries outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

***The FDA may not ultimately approve our proposed trade names for our product candidates.***

Any trade names that we intend to use for our product candidates must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or PTO. The FDA conducts a rigorous review of proposed product names and may reject a proposed product name for a variety of reasons, including if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. In addition, if the FDA determines that the trade names of other product candidates that are approved prior to the approval of our product candidates may present a risk of confusion with any of our proposed trade names, the FDA may not ultimately approve those proposed trade names. If the FDA does not approve any of our proposed product names prior to their applicable NDA approval dates, we may be required to launch commercial sales of such products without brand names, and our efforts to build successful brand identities for, and commercialize, such products may consequently be adversely impacted.

***Any product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization.***

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. In addition, the FDA or other regulatory authorities may require, or we may undertake, additional clinical trials to support the safety profile of our product candidates.

In addition, if any product candidate that we may develop that receives marketing approval and we or others later identify undesirable side effects caused by the product, or there is a perception that the product is associated with undesirable side effects:

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

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regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed; and

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy.

If any of these events occurred with respect to our product candidates, our ability to generate significant revenues from the sale of these products would be significantly harmed.

***Delays in the commencement or completion of clinical trials, or suspension or termination of our clinical trials, could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.***

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed or limited. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of study sites and enroll a sufficient number of patients at such sites. We do not know whether enrollment in our future clinical trials for our product candidates will be completed on time, or whether our additional planned and ongoing clinical trials for our product candidates will be completed on schedule, if at all.

The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays in:

obtaining regulatory approval to commence or amend a clinical trial;

reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

recruiting and enrolling patients to participate in clinical trials;

retaining patients who have initiated a clinical trial but who may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues or side effects from the therapy or who are lost to further follow-up;

manufacturing sufficient quantities of a product candidate; and

IRB approval or approval from foreign counterparts to conduct or amend a clinical trial at a prospective site.

In addition, a clinical trial may be delayed, suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

inspections of our own clinical trial operations, the operations of our CROs or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or potentially prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;

our failure or inability, or the failure or inability of our CROs, clinical trial site staff or other third party service providers involved in the clinical trial, to conduct clinical trials in accordance with regulatory requirements or our clinical protocols;

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- lower than anticipated enrollment or retention rates of patients in clinical trials;
- new information suggesting unacceptable risk to subjects or unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials; and
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

If we experience delays in the completion of our clinical trials for a product candidate, the commercial prospects for such product candidate may be harmed, we may incur increased costs for development of such product candidate and our ability to obtain regulatory approval for such product candidate could be delayed or limited. Many of the factors that cause or lead to delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. In addition, any amendment to a clinical trial protocol may require us to resubmit our clinical trial protocols to IRBs or their foreign counterparts for reexamination, which may delay or otherwise impact the costs, timing or successful completion of a clinical trial.

***The loss of any rights to develop and market any of our product candidates could significantly harm our business.***

We license the rights to certain compounds to develop and market our product candidates. Currently, we have licensed rights relating to eight compounds for the development of ten product candidates.

We are obligated to develop and commercialize certain product candidates in accordance with mutually agreed upon terms and conditions. Our ability to satisfy some or all of the terms and conditions of our license agreements is dependent on numerous factors, including some factors that are outside of our control. Any of our license agreements may be terminated if we breach our obligations under the agreement materially and fail to cure any such breach within a specified period of time.

If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate that is the subject of the license. The termination of the license agreements related to either of our two prioritized product candidates would significantly and adversely affect our business. The termination of any of the remainder of our license agreements could materially and adversely affect our business.

***If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.***

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the U.S. and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. We cannot assure you that developments by others will not render our product candidates obsolete or noncompetitive. Many of our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer, more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any products that we are able to obtain approval for, if at all. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

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In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources, including personnel and technology, clinical trial experience, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates.

***We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates if we are able to achieve such third-party arrangements.***

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. Following completion of the Phase 2 clinical trial for MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of Avigen in December 2009, we do not plan to undertake any further significant clinical development activities for any of our product candidates other than MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, other than those activities deemed necessary to maximize each product candidate s value, until such time that we are successful in entering into a partnership or collaboration for further development of such product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations or otherwise monetize these product candidates on acceptable terms, if at all.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise. Even if we are successful in entering into a strategic collaboration for one of our product candidates, our partner may fail to develop or effectively commercialize the product candidate because such partner:

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determines that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We also face competition in our search for partners from other biotechnology and pharmaceutical companies worldwide, many of whom are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting partners and entering into collaborations on acceptable terms for these product candidates or otherwise monetizing these product candidates, we may not be able to complete development of or obtain regulatory approval for such product candidates. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered.

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***The terms under which we raise additional capital or debt financing may harm our business and may significantly dilute stockholders ownership interests.***