Takashi Kiyoizumi, M.D., Ph.D. President and Chief Executive Officer MediciNova, Inc. 4350 La Jolla Village Drive, Suite 950 San Diego, CA 92122

Re: MediciNova, Inc.

Registration Statement on Form S-1

File Number 333-119433

Dear Dr. Kiyoizumi:

We have reviewed your filing and have the following comments. Where indicated, we think you should revise your document in response to these comments. If you disagree, we will consider your explanation as to why our comment is inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with supplemental information so we may better understand your disclosure. After reviewing this information, we may or may not raise additional comments.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filing. We look forward to working with you in these respects. We welcome any questions you may have about our comments or on any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

### Form S-1

Comments Applicable to the Entire Prospectus

- 1. We note your statement in the exhibit list that you intend to apply for confidential treatment for certain of your exhibits. Please note that comments related to your request for confidential treatment will be delivered under separate cover. Please be advised that we will not be in a position to consider a request for acceleration of effectiveness of the registration statement until we resolve all issues concerning the confidential treatment request.

  2. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments
- 3. Please note that when you file a pre-effective amendment that includes your price range, it must be bone fide. We interpret this to mean that your range may not exceed \$2 if you price below \$20 and 10% if you price above \$20.
- 4. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note we may have comments regarding this material.
- 5. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.

Table of Contents, page i

- 6. You should retain only the Table of Contents on this page. All other information should be disclosed after the Risk Factors section. Prospectus Summary, page 1
- 7. As you have chosen to include a summary of your strategy, please revise to include a discussion of the risks and obstacles you must address in implementing this strategy.

Risks Affecting Our Business, page 2

8. Please revise this discussion so that it is in a bullet-point format.

Risk Factors, pages 7-22

9. Your risk factor section is 16 pages long and contains a lot of duplicative information. Please reduce it to eliminate overlapping

or duplicative information. For example, please note the following:

- \* It appears that the risks discussed in the 3rd, the 6th, the 7th, and the 11th risk factors overlap relating to your ability to develop and commercialize a therapeutic drug successfully. Please consider combining these risk factors to reduce the redundancy.
- \* It appears the risks discussed in the 18th and 19th risks factors discuss similar issues related to your reliance on third parties to manufacture your products. Please consider combining these risk factors to reduce the redundancy.
- \* It appears that the risks discussed in the 22nd, 23rd and 24th risk factors discuss similar issues and risks related to protecting your proprietary risks. Please consider combining these risk factors to reduce the redundancy.
- \* It appears the risks discussed in the 23rd and the 28th risks factors discuss similar risks related to your ability to obtain and maintain your patent protection and other proprietary rights. Please consider combining these risk factors to reduce the redundancy.
- \* It appears the risks discussed in the 25th and 26th risk factors discuss similar risks related to litigation involving proprietary or the proprietary rights of others. Please consider combining these risks factors to reduce the redundancy.
- "Unless we are able to generate sufficient product revenue, we will continue . . . ," page 7  $\,$
- 10. We note your disclosure that you received revenue from the performance of "development management services." Please describe what development management services you performed.
- 11. In addition, please identify to whom you provided these services to, and whether you expect to continue to provide such management services.
- "If we fail to develop and commercialize a therapeutic drug successfully, we . . . .," page 7  $\,$
- 12. Please revise your risk factor heading to disclose that you have no products available for commercial sale.
- "The loss of any rights to develop and market any of our product candidates . . . ,," page 7  $\,$
- 13. Please identify the parties that you currently maintain any material license agreements with as well as the product candidates that you have licensed.
- "If we fail to identify and license or acquire product candidates, we will not be . . . .," page  $8\,$
- 14. Please revise your risk factor to disclose that you may not have the necessary funds or resources to complete acquisitions, and that if you are able to do acquisitions that you may not successfully integrate the acquired company or technology with your own. You should also highlight your lack of experience in identifying and completing acquisitions.
- "If we fail to obtain the capital necessary to fund our operations, we will be . . . .," page 9
- 15. Please divide this risk factor into two risk factors: one addressing the consequences of not obtaining sufficient capital and the other addressing the negative consequences of obtaining capital, such as dilution. It may be appropriate to combine the second risk factor with "If we raise additional capital in the future, your ownership in us could be diluted" on page 19.
- 16. If you do not raise the anticipated offering amount, please indicate how long you could continue to run your operations. We note your have provided for this disclosure in your Liquidity and Capital Resources discussion.
- "We will depend on strategic collaborations with third parties to develop and . . . .," page 10  $\,$
- 17. Based on our reading of this risk factor and your Business section, it is unclear whether you have entered into any strategic collaboration with third parties to develop and commercialize any of your product candidates. Please revise your disclosure to clarify

whether you have or have not. If you have not, please also indicate when you anticipate you would enter into such arrangements.

- "We rely on third parties to conduct our clinical trials and perform data  $\ .\ .\ .\ .,$  " page 10
- 18. Please identify the third parties you rely on to conduct your clinical trials and perform data collection and analysis. Please also describe the material terms of any agreements you have with such entities in the Business section of your document. You should also file the agreements as exhibits.
- 19. Please indicate if any of the factors you have described in this risk factor have delayed, suspended or terminated any of your clinical trials. If so, please briefly describe the specific circumstances and how they impacted the Company.
- "If we are unable to attract, retain and motivate key management and scientific . . . .," page 11
- 20. Since most companies rely on their key personnel, clearly explain how this specific risk factor applies to your company. For example, identify the key personnel upon whom you are dependent and how you would be adversely affected if one or more of them left.
- 21. To the extent that you have experienced problems attracting and retaining key personnel in the recent past, please revise to describe these problems. Additionally, if any key employee has plans to retire or leave your company in the near future, please revise the discussion to disclose this information.
- 22. In addition, please discuss any aspects of your business that make you less attractive than other companies to potential employees.
- "We may not be able to continue to exploit the services of outside scientific . . . .," page 12
- 23. Describe briefly the rights that your outside and clinical advisors have to publish data and information.
- "We will need to increase the size of our organization, and we may encounter . . . ," page 12  $\,$
- 24. To the extent you can, please quantify the extent of your growth and expansion and the time period to which you refer in this risk factor.
- Relying on third party manufacturers may result in delays in our clinical trials . . . .," page 13
- clinical trials . . . , " page 13 25. Please indicate if these parties currently meet your manufacturing requirements.
- "Materials necessary to manufacture our products may not be available on . . . ," page 13  $\,$
- 26. Please identify the suppliers that you or your manufacturers substantially rely on for the production of the compounds you need for preclinical and clinical purposes. To the extent you have any formal agreements with them, please provide the material terms of the agreements and file the agreements as exhibit to your document. If you do not have any long term agreements, please disclose this information and disclose when any short-term supply agreements expire.
- 27. If difficulties in obtaining needed supplies has ever caused a material delay or disruption to your business, please discuss.
- "Our success depends upon our ability to protect our intellectual property . . . .," page 14
- 28. Please describe your patents for any key products and the expiration date of such patents. In your Business section, provide an expanded discussion to include the number of patents you have, the number of patent applications you have filed as well as the number of patents licensed to you.
- 29. In addition, with respect to patents you obtained from third parties, please disclose who has the obligations to take necessary actions to protect patents under your license agreements. If you do not have the obligation to take action, do you have the right to take necessary actions if the other party does not?
- "Confidentiality agreements with employees and others may not adequately . . . .," page 15
- 30. If your business has been materially and adversely affected by the disclosure of proprietary information, please discuss the situation and its consequences.
- If our competitors develop and market products that are more effective than . . . .," page 17  $\,$
- 31. If you are aware of any specific competition, products in development or new products that your competitors provide or will

soon provide, disclose these competitive threats and the potential impact of these products or product introductions on your business. Also, you should consider naming your most relevant competitors whose business activities could have a material adverse effect on your prospects or business going forward. If there are too many competitors to name, please disclose the approximate number of competitors in your target markets.

"Rapid technological change could make our products obsolete," page

Health care reform measures could adversely affect our business," page 18

"We will incur increased costs as a result of recently enacted and proposed . . . .," page 20

32. As currently written, these risk factors could apply to any issuer or offering. See Item 503(c) of Regulation S-K. While we understand that the risks you describe in this subsection are risks the company encounters because it is in the drug development business, you should state how this risk relates specifically to your company.

"Consumers may sue us for product liability, which could result in substantial . . . .," page 17

- 33. Please disclose the amount of your insurance coverage, or in the alternative, please indicate if you believe such coverage amount is reasonably adequate to insulate you from potential product liability claims.
- "If our stockholders sell substantial amounts of our common stock after this  $\dots$ ," page 20
- 34. Please disclose the number of shares that are subject to lock-up agreements.
- 35. In addition, please revise to include information about the registration rights agreement described on page 64 pursuant to which additional shares of common stock could be registered for resale by shareholders.
- "As a new investor, you will experience immediate and substantial dilution in . . . . ," page 20  $\,$
- 36. Please revise this risk factor to explain that investors who purchase shares will:
- \* Pay a price per share that substantially exceeds the value of your assets after subtracting its liabilities; and
- \* Contribute \_\_\_% of the total amount to fund the company but will own only \_\_\_% of the outstanding share capital and \_\_\_% of the voting rights.
- "We have never paid dividends on our capital stock, and we do not . . . .," page 22  $\,$
- 37. Please be advised that so far as the risk to investors is concerned, this risk states that you will not pay dividends, which is not a risk by itself to investors. Clearly state that readers should not rely on an investment in your company if they require dividend income and an income to them would only come from any rise in the market price of your stock, which is uncertain and unpredictable Information Regarding Forward-Looking Statements, page 23 38. We note your statement that you the information derived from third party sources "do not guarantee the accuracy or completeness of the information" and that you have "not verified independently the data and make no representation as to the accuracy of the data." It is not appropriate to disclaim liability for statements included in your registration statement. Please revise to delete this language.

Use of Proceeds, page 24

39. Please disclose the approximate amount and timing of the proceeds you plan to use for the purposes you list in this section, including how much you anticipate spending of each of your leading product candidates. Please also indicate where in the drug development process you expect to be after the expenditure of these proceeds. 40. Please disclose more specific information as to the use of working capital. For example, will you acquire new product candidates, or expand your facilities?

Management`s Discussion and Analysis of Financial Condition, page 28 Research and Development Expense, page 28

41. Please refer to the Division of Corporation Finance "Current Issues and Rulemaking Projects Quarterly Update" under section VIII - Industry Specific Issues - Accounting and Disclosure by Companies Engaged in Research and Development Activities. You can find it at the following website address:

Please disclose the following information for each of your major research and development projects:

- \* The costs incurred during each period presented and to date on the project;
- \* The nature, timing and estimated costs of the efforts necessary to complete the project;
- \* The anticipated completion dates;
- \* The risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if the project is not completed timely; and finally \* The period in which material net cash inflows from significant projects are expected to commence.

To the extent that information requested above is not known or estimable, disclose that fact and the reason why it is not known.

42. We note your disclosure that the only revenues you have generated to date have been from a development management contract. Please identify the party to whom you have this contract, and disclose whether you expect this revenue source to continue for the next 12-18 months, and your reason for this expectation.

Critical Accounting Policies and Estimates

43. It appears accruals for external services and contract research organization costs provided by others on your behalf would require significant estimates/judgments. Refer to Note 1 (Research and Development expenses) on page F-9. Please consider revising your critical accounting estimate and consider the following factors in your discussion:

- \* How the company arrived at the estimate
- \* How accurate the estimate/assumption has been in the past
- \* How much the estimate/assumption is reasonably likely to change in the future

Results of Operations, pages 30-31

Comparison of the Six Months Ended June 30, 2004 and 2003 44. When more than one reason is responsible for a fluctuation, you should quantify each of the factors causing the change. In this regard, you note several reasons for your increase in research and development expenses from 2003 to 2004 (i.e. external costs related to licensing, increased Phase I clinical study costs and increased pre-clinical development costs, etc.) and several reasons for you increase in general and administrative expenses (i.e. legal, other professional fees and personnel costs, etc). Please quantify the effects of each factor on the increases and decreases in a line item being discussed. Revise throughout Management's Discussion and Analysis for all periods presented.

Liquidity and Capital Resources

45. In accordance with SEC Release No. 33-8183, please provide table of contractual obligations. The table should disclose the amounts of payments due under specified contractual obligations, aggregated by category of contractual obligation, for specified time periods. Please consider all contractual obligations, including upfront and milestone payments and royalties discussed in Note 5 on page F-14.

Comparison of the Years Ended December 31, 2003, 2002 and 2001, page 31

Research and Development, page 31

46. Please explain what your store-operated calcium channel program is. In addition, please explain why you reduced the scope of the store-operated calcium channel program in 2003? Please also indicate if you intend to further reduce your activities in this program, and the reasons for your decision.

Business, page 33

- 47. Throughout this section, you reference several industry sources and various statistics and other figures. Please provide us with any copies of all sources cited. Please note that copies delivered should be marked to highlight the relevant information.
- 48. To the extent applicable, please include information about compliance with environmental laws, as required by Item 101(c)(1)(xii) of Regulation S-K. Additionally, if you are subject to any environmental laws, please consider adding a risk factor discussing the risks and consequences of activities dealing with any environmentally hazardous materials. If you are not subject to any environmental laws, please briefly explain to us why you are not

subject to such laws.

Strategic Core Programs, page 36

MN-221 for Premature Labor, page 36

49. We note your disclosure that "[p]re-clinical pharmacology studies conducted by Kissei Pharmaceutical have shown that MN-221 effectively suppresses spontaneous or drug induced uterine contractions." Please revise to state whether these results are statistically significant and also state that further testing may fail to confirm the results of the studies. In addition, please make similar revisions for your other products where you provide similar pre-clinical testing results.

MN-001, page 37

50. In the first paragraph of this section, you make several claims relating to the efficacy of your MN-001 and MN-002 products. Please briefly describe the studies on which these statements are based. If the studies did not involve human subjects, state what the subjects were. We may have further comments.

MN-029, page 37

51. In section, you make several claims relating to your MN-029. Please briefly describe the studies on which these statements are based. If the studies did not involve human subjects, state what the subjects were. We may have further comments.

MN-001, page 38

52. In the first paragraph of this section, you make several claims relating to the efficacy of your MN-001 product. Please briefly describe the studies on which these statements are based.

MN-305, page 39

53. Please disclose, if true, that that you did not perform any study on the reduction of anxiety symptoms that were not treated with your MN-305.

Store-Operated Calcium Channel Antagonist Discovery Program, page 39 54. Please identify the "recent studies" that support the idea that SOCCs may be responsible for the calcium influx during T cell activation as well as the "recent studies" that suggests a blockade of SOCCs can slow the proliferation of cancer cells. In addition, please provide us with copies of these sources marked to show where the statements supporting your claims are provided for.

License and Master Services Agreements, page 40

55. Please disclose the term of each of the agreements discussed in this section. In addition, please disclose when the license patent for each of your licensing agreements expires.

56. In addition for each of the license agreements, please also disclose any payments received/made to date; additional aggregate potential payments; and any revenue sharing arrangements. Please note that aggregate licensing and aggregate milestone payments should also be disclosed and quantified.

Manufacturing, page 42

57. Please tell us what your arrangement is with each of the manufacturers discussed in this section, including the rights and responsibilities of each party. In addition, you should disclose the term of the agreement and any purchase commitments, if applicable. In the alternative, please give us a detailed explanation of the reasons you do not believe any of your arrangements with your current manufacturers are material to you.

Competition, page 47

58. Please expand the discussion to include the development of emerging technologies or products that may compete with you and the current stage of development of these technologies or products.

Employees, page 48

59. Please disclose the number of part-time employees you have, if any.

Facilities, page 48

60. Please disclose the amount of your annual lease payments and when the lease agreement expires. You should also file the lease agreement as an exhibit to your registration statement.

Management, page 49

61. Please note that Item 401 of Regulation S-K requires a brief description of the business experience of your officers and directors

during each of the last five years. Please revise this section to include the applicable dates for Richard E. Gammans, Mark Lotz, and Daniel Vapnek.

Employment Agreements and Change in Control Arrangements, page 56 62. Please revise your disclosure to include the following to the extent applicable:

- \* Does Dr. Kiyoizumi`s employment agreement have a renewable term beyond the initial period?
- \* Are the annual salaries of each of the executive officers described in this section determined annually by the board?
- \* Briefly describe any restrictive covenants, including the nondisclosure and non-competition obligations contained in each of the employment agreements described in this section.

### Related-Party Transactions, page 59

- 63. Please state whether each transaction described in this section was on terms as favorable as could have been obtained through unrelated parties.
- 64. Please revise your Management section to provide the material terms of the consulting agreement you have with Dr. Iwaki. In addition, you should file the agreement as an exhibit to your registration statement.

# Principal Stockholders, page 61

65. Please provide the full name(s) of the natural persons having voting, dispositive or investment powers over the shares held by each of your stockholders owning more than 5% of your common stock.

Description of Capital Stock, page 63

#### Common Stock, page 63

66. Please state the expiration date of the options, and state whether the expiration date may be extended and, if so, how.

### Warrants, page 64

67. Please state the expiration date of the warrants, and state whether the expiration date may be extended and, if so, how. Please also clarify whether the warrants are callable and, if so, how and when you could call the warrants.

# Underwriting, page 75

- 68. Please indicate if your underwriters have arrangements with a third party to host or access your preliminary prospectus on the Internet. If so, identify the party and provide the address of the website. Please also describe the material terms of the agreement and provide us with a copy of any written agreement. You should also provide us with copies of all information concerning your company or the offering that appears on the third party web site. We may have further comments.
- 69. If the lead underwriters or other members of the syndicate may deliver a prospectus electronically or otherwise offer and/or sell securities electronically, please tell us the procedures they will use and how they intend to comply with the requirements of Section 5 of the Securities Act of 1933, particularly with regard to how offers and final confirmations will be made and how and when purchasers will fund their purchases. Provide us copies of all electronic communications including the proposed web pages.
- 70. Also tell us and briefly disclose in the prospectus whether you intend to use any forms of prospectus other than print, such as CD-ROM-s, videos, etc. and provide all such prospectuses for our examination. Please refer to SEC Releases No. 33-7233 and No. 33-7289. We may have additional comments.
- 71. If you intend to do a directed share offering, please provide us with any material you intend to sell to potential purchasers such as a "friends and family" letter. Tell us when you intend to send them to these potential purchasers. Tell us whether the sale will be handled by you directly or by the underwriting syndicate. Tell us the procedures you or the underwriter will employ in making the offering and how you will assure that this offer will meet the requirements of Section 5 of the Securities Act and Rule 134. We may have further comments.

### Financial Statements and Related Footnotes

- 72. Please note that in your first Form 10-K the auditors` report should cover the period from inception through the most recent fiscal year completed. Refer to SFAS 7.
- 73. Please provide an analysis of how you determined the fair value of your stock compensation in 2004 and how you determined the amount to record for your deemed dividend to be recorded in the third quarter of 2004.

Statements of Operations, page F-4
74. Please revise the face of the Statements of Operations to specifically state what line items "Stock-based compensation related to founders` warrants" relate (i.e. research and development, general and administrative, etc.). Also, revise the related disclosures throughout the document.

Note 1. The Company, Basis of Presentation and Summary of Significant Accounting Policies
75. Please disclose the Company's revenue recognition policy.

Note 6. Stockholders` Equity, page F-15

Founders` Common Stock and Warrants

76. Please disclose what event(s) triggered the anti-dilution provision adjustment of the common stock warrants up to 3,650,000 shares of common stock. Also, please disclose what factors were considered when determining the fair value of the underlying shares of common stock.

### Other Warrants

77. Please disclose to whom the other warrants were issued to as compensation for fundraising efforts. Also, please clarify if any compensation was recorded and if not, supplementally tell us why management felt it was appropriate not to recognize any compensation expense related to the warrants.

Item 15. Recent Sales of Unregistered Securities, page II-2 78. Please revise to identify all of the investors in the unregistered offering you describe in paragraph one of this section.

#### Exhibite

79. Please file your remaining exhibits, including the legal opinion with your next amendment or as soon as it becomes available as we will review it prior to granting effectiveness of the registration statement

80. Please revise the footnote about your confidential treatment request to state that portions of the exhibits have been omitted pursuant to a confidential treatment request and that this information has been filed separately with the Commission.

\* \* \*

As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested supplemental information. Detailed cover letters greatly facilitate our review. Please file your cover letter on EDGAR under the form type label CORRESP. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filings reviewed by the staff to be certain that they have provided all information investors require for an informed decision. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event the company requests acceleration of the effective date of the pending registration statement, it should furnish a letter, at the time of such request, acknowledging that

\* should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;

\* the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and

\* the company may not assert this action as defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in connection with our review of your

filing or in response to our comments on your filing.

We direct your attention to Rules 460 and 461 regarding requesting acceleration of a registration statement. Please allow adequate time after the filing of any amendment for further review before submitting a request for acceleration. Please provide this request at least two business days in advance of the requested effective date.

You may contact Dana Hartz at (202) 942-2976 or Mary Mast (202) 942-1858 if you have questions regarding comments on the financial statements and related matters. Please contact Song Brandon at (202) 942-2831 or John Krug at (202) 942-2979 with any other questions.

Sincerely,

Jeffrey Riedler Assistant Director

cc: Babak Yaghmaie, Esq. Pillsbury Winthrop LLP 1540 Broadway New York, NY 10036