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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): March 21, 2005

MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-51133**	**33-0927979**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4350 La Jolla Village Drive, Suite 950
San Diego, CA 92122
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (858) 373-1500

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On March 22, 2005 (Japanese Standard Time), MediciNova, Inc. (the "Company") filed with the Osaka Securities Exchange a Japanese report referred to as "Kessan Tanshin," which contained, among other things, its financial results for the fiscal year ended December 31, 2004 (the "Japanese Filing"). A copy of the certified English translation of the Japanese Filing is attached hereto as Exhibit 99.1.

The information in this Form 8-K and the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. The information in this Form 8-K shall not be incorporated by reference into any registration statement or filing of the Company, except as shall be expressly set forth by specific reference in such a filing.

The Japanese Filing may contain "forward-looking statements" as defined by the Securities and Exchange Commission (the "SEC"). All statements, other than statements of historical facts, included in the Japanese Filing that address activities, events or developments that the Company expects, believes or anticipates will or may occur in the future are forward-looking statements. These statements are based on certain assumptions made by the Company based on management's experience and perception of historical trends, current conditions, expected future developments and other factors it believes are appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond the control of the Company, which may cause the Company's actual results to differ materially from those implied or expressed by the forward-looking statements. These forward-looking statements speak only as of the date hereof. In addition, the risk factors contained in the Japanese Filing do not contain all of the risk factors set forth in the Company's Registration Statement on Form S-1 (the "Registration Statement") filed by the Company with the SEC. For a discussion of factors that may cause results to differ, please see the Company's SEC reports, including its Special Financial Report for the year ended December 31, 2004 and the Registration Statement.

Item 7.01. Regulation FD Disclosure.

The Company will hold a live Japanese language meeting at Tokyo Shoken Kaikan 9F on Wednesday, March 23, 2005 (Japanese Standard Time) to discuss the Company's financial results for the fiscal year ended December 31, 2004 and the contents of the Japanese Filing. The meeting will be made available by webcast on the Osaka Securities Exchange website promptly following the meeting. A link will be posted to the Company's website to permit access to the webcast.

The information in this Form 8-K and the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. The information in this Form 8-K shall not be incorporated by reference into any registration statement or filing of the Company, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit	Description
99.1	Certified English translation of Japanese Filing dated March 22, 2005.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 21, 2005

MEDICINOVA, INC.

By: /s/ Takashi Kiyoizumi

Takashi Kiyoizumi, M.D., Ph.D.
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Certified English translation of Japanese Filing dated March 22, 2005.

Financial Statements For the Year Ended December 31, 2004

March 22, 2005

Name of Listed Company: MEDICINOVA, INC.
Code Number: 4875
(URL http://www.medicinova.com)
Representative Officer: Takashi Kiyoizumi, President & CEO
Contact: Joji Suzuki, Vice President, Finance, TEL: (03) 5532-7406
Date of Meeting of Board of Directors for Approving Financial Statements: March 22, 2005
Interim Dividend System: N/A
Date of Annual Meeting of Shareholders: To be decided
System of trading unit of shares: Adopted (Unit: 1,000 shares)

Listed Exchanges: Hercules, Osaka Ex.
Location of Head Office: California, U.S.A.

1. The financial statements for the years ended December 31, 2004 and 2003 are prepared in accordance with accounting principles generally accepted in the United States (U.S.). Unless otherwise noted, all amounts are expressed in U.S. dollars.

(1) Operating Results

	Revenues	Operating Loss	Net Loss
Year ended December 31, 2004	490,282	(48,612,386)	(48,272,603)
Year ended December 31, 2003	—	(6,261,103)	(6,209,130)

	Net Loss	Net Loss Per Share	Ratio of Net Loss to Stockholders' Equity	Ratio of Operating Loss to Total Assets	Ratio of Operating Loss to Sales
Year ended December 31, 2004	(48,272,603)	(159.23)	788.8%	163.7%	9,915.2%
Year ended December 31, 2003	(6,209,130)	(12.42)	218.2%	173.5%	—

(Notes)
(a) Profit (loss) from investment by equity method:
Year ended December 31, 2004: N/A
Year ended December 31, 2003: N/A
(b) Weighted average number of outstanding shares of common stock during:
Year ended December 31, 2004: 500,000 shares
Year ended December 31, 2003: 500,000 shares
(c) Changes in accounting method: None
(d) Percentages shown for revenues, operating loss, and net loss in tables above are percentages of change from the previous year.

(2) Dividends

	Annual Dividend Per share		Aggregate (annual) Dividends Paid	Pay Out Ratio	Ratio of Dividends to Stockholders' Equity
	Interim Dividend	Year-end Dividend			
Year ended December 31, 2004	—	—	—	—	—
Year ended December 31, 2003	—	—	—	—	—

(3) Financial Condition

	Total Assets	Stockholders' Equity	Equity Ratio (Ratio of equity to total assets)	Stockholders' Equity Per Share
			%	
As of December 31, 2004	53,768,595	7,669,122	14.3	15.34
As of December 31, 2003	5,631,309	4,569,882	81.2	9.14

(Notes)

(a) Shares of common stock outstanding as of:
December 31, 2004: 500,000 shares
December 31, 2003: 500,000 shares

(b) Repurchased shares as of:
December 31, 2004: 0 shares
December 31, 2003: 0 shares

(4) Cash Flow

	Net Cash Used in Operating Activities	Net Cash Used in Investing Activities	Net Cash Provided by Financing Activities	Cash and Cash Equivalents at the Year-end
Year ended December 31, 2004	(13,546,476)	(11,071,235)	59,178,340	38,801,328
Year ended December 31, 2003	(5,931,250)	(1,065,716)	9,956,547	4,240,699

2. Financial Results Forecast for the six months ending June 30, 2005 and the Year Ending December 31, 2005

	Revenues	Operating Loss	Net Loss	Annual Dividend Per Share	
				Interim Dividend	Year-end Dividend
Interim Period (6 months)	42,200	(18,600,000)	(17,000,000)	—	—
Full Year	750,000	(40,900,000)	(37,700,000)	—	—

(Reference) Expected loss per share (for full year): $0.39

* Using 95,690,401 for the weighted average number of shares used for expected basic and diluted loss per share.

Notes to use or disclosure of financial results forecast.

The above estimates are based on certain assumptions made by the Company's management as of the date hereof. These assumptions are based on management's experience and perception of current conditions, trends, expected future developments and other factors believed to be appropriate in the circumstances. Such estimate is subject to a number of assumptions, risks and uncertainties, many of which are beyond the control of the Company, which may cause the Company's actual results to differ materially from the above estimates. These risks include the risk factors detailed in the Company's Securities and Exchange Commission filings. Our independent auditors have not compiled or been involved in the preparation of the forecasted results for 2005. Accordingly, they assume no responsibility for the accuracy or presentation of this information.

1. Corporate Group

There is nothing to be noted regarding a corporate group because MEDICINOVA, INC. (hereinafter the “Company,” “we,” “our” or “us”) has no affiliated companies.

2. Management Policies

2.1. Basic Management Policy

The Company aims at becoming a global pharmaceutical company specialized in acquiring, developing and selling innovative drugs for diseases and conditions with no established effective treatment. In seeking and acquiring license to product candidates, the Company follows its basic policy that:

- a product candidate should be in the late pre-clinical or early clinical development stage and should have extensive safety and efficacy data, and
- the product candidate should have a large potential market and have significant potential to improve treatment effect.

2.2. Basic Policy for Profit Sharing

While there are no plans to do so in the foreseeable future, the Company will pursue maximization of stockholders’ value when it distributes profit. However, the Company is still at the early stage of business development. It is our policy for the time being to retain earnings to appropriate them for the growth and development of the operations.

2.3. Reducing the Investing Unit

The Company may determine that it has become necessary and important to reduce the investing unit according to the future upward movement of the Company’s share price in order to encourage more investment by investors and to increase the liquidity of the Company’s shares.

2.4. Target Management Indices

It is expected that the Company will continue to report net loss at least for the next several years. Accordingly, we believe that it is inappropriate to use financial indices as business management targets of the Company for the time being. Moreover, we believe it is also inappropriate to use non-financial indices such as the development progress of product candidates as targets because they are not established as standard indices.

2.5. Mid- and Long-Term Business Strategy

The Company seeks to be a pioneer in developing and selling therapeutic drugs for diseases for which effective treatments have not been established. Major strategies include:

- *Dual pathway development approaches*

  The Company has acquired rights in various product candidates that are based on proven pharmacology, but have features distinct from existing treatments. In developing these product candidates, the Company uses two different approaches: strategic core programs and partnering programs. We believe that these approaches enable us to diversify our development risks with respect to these product candidates. The intention is to advance development of existing and future product candidates without excessive reliance on any single program and thereby to increase the likelihood of long-term success. Moreover, we believe that this dual pathway development approach significantly enhances our ability to generate near-term revenue opportunities through

the partnering programs, and long-term sustained revenue opportunities through strategic core programs.

- *Continuous expansion of pipelines for promising product candidates*

  The Company continues to identify and acquire licenses for product candidates in the late pre-clinical or early clinical development stage. The Company utilizes its industry contacts to identify and acquire product candidates with high potential and extensive pre-clinical or early clinical data from Japanese pharmaceutical companies, which is one of our advantages over other specialty drug companies in the U.S. market. The Company is in active negotiations to acquire licenses for additional product candidates, making the best use of this advantage. In pursuing licenses for product candidates, the Company conducts extensive examinations not only on the patent rights and therapeutic needs addressed, but also on the market opportunities, level of competition and strategic fit with existing programs. We believe that risks inherent in drug invention and development will be mitigated by expanding and further diversifying of our pipelines of product candidates.

- *Partnership with selected major drug companies to maximize the commercial potential of product candidates*

  The Company intends to actively pursue strategic collaborations with major biotechnological or pharmaceutical companies to draw on their expertise on development, pharmaceutical regulation and commercialization. The Company has made contact with several companies that have shown interest in its partnership program. In the area of the strategic core programs, we will continue to seek additional licensors of product candidates, potential co-marketing partners and potential future licensees outside the U.S. market. Once favorable results are obtained in the clinical trial stage for product candidates developed through these efforts, we will endeavor to realize a quick return on our investment.

- *Continuous strengthening of the management team*

  While developing the existing product candidate portfolio, the Company have also carefully assembled a management team of leaders with extensive experience in all aspects of the drug development process from acquisition of product candidates through commercialization. The management team will be further strengthened in the near future by adding selected leaders who will contribute to the improvement of our core competencies and the fastest implementation of our development programs.

2.6. Issues To Be Addressed

The Company must steadily carry out business strategies described in Section 2.5. In pursuing these strategies, the following risks may adversely effect the business of the Company:

2.6.1. Risks Related to the Business

2.6.1.1. *Consecutive net loss is expected for at least several years and the extent of the future loss is unforeseeable.*

We are a specialty pharmaceutical company still in the development stage with a limited operating history. We have incurred significant net losses since our inception. For the year ended December 31, 2003, we had a net loss of $6.2 million. For the year ended December 31, 2004, we had a net loss of $48.3 million, including $34.3 million of non-cash stock-based compensation charges related to employee stock options and warrants issued to the founders. We expect annual net losses to increase over the next several years as we expand and incur significant clinical development costs. These losses have reduced our stockholders' equity, and, excluding the portion related to non-cash warrant-based compensation, will continue to reduce our stockholders' equity and working capital. Development

expenses are expected to increase in connection with our planned clinical trials for product candidates and any other development projects that we may initiate. In addition, the general and administrative expenses and expenses necessary to operate as a public company are also expected to increase. Consequently, it is expected that significant and incremental operating losses will be recorded for the foreseeable future.

2.6.1.2. *At present, the Company has no products that are approved for commercial sale and therefore we do not expect any revenues from product sales in the foreseeable future.*

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. To date, we have not earned any product revenue and have funded our operations primarily from private sales of our securities. The only source of revenues of 2004 was from development management services rendered to Asahi Kasei Pharma Corporation and Argenes Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. In 2003, we earned no revenues. The Company anticipates that it will continue to receive modest revenues for rendering consulting services. Prior to commercialization of a product candidate, consulting revenues, together with strategic collaboration fees and upfront and milestone payments related to out-licensing will be our primary source of revenues. To obtain revenues from sales of product candidates, the Company must succeed, either alone or with third parties, in obtaining regulatory approval for the development, manufacturing and marketing of drugs with market potential. There is a risk that we may not succeed in these activities or may not generate sufficient revenues to support continuing business operations or to achieve profitability.

2.6.1.3. *The loss of any rights to develop and market any product candidate would significantly impair our operating results*.

The Company has acquired several licenses to develop and sell product candidates. Currently, the Company is a licensee for the following six compounds that are incorporated in the development of our seven product candidates.

- MN-221 for premature labor licensed from Kissei Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;
- MN-001 for interstitial cystisis and asthma licensed from Kyorin Pharmaceutical;
- MN-305 for anxiety licensed from Mitsubishi Pharma Corporation;
- MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical; and
- MN-246 for urinary incontinence licensed from Mitsubishi Pharma Corporation.

We are obligated to develop and commercialize these product candidates in accordance with terms and conditions agreed with licensors. Fulfillment of some or all of the terms and conditions of the license arrangements is dependent on numerous factors, including some factors that are beyond the control of the Company. These license arrangements may be terminated if we materially breach our obligations thereunder and fail to correct the breach within a specified period of time. If any of the license agreements is terminated, then we would have no further rights to develop and commercialize the licensed product candidate. The termination of any license agreement may significantly and adversely affect our business.

2.6.1.4. *In order to commercialize a therapeutic drug successfully, a product candidate must undergo long, complex and costly clinical trials that have high risk of failure or may be delayed or suspended.*

All of our product candidates are in the clinical development stage and require regulatory approval for commercial sale. The regulatory approval process is long, complex and costly. It often takes several

years to complete the clinical development necessary to commercialize a drug, and delays or failure may occur at any stage that may result in failure to generate revenues from marketing and sales of products derived from product candidates. Of the large number of drug candidates being developed by pharmaceutical companies only a small percentage result in the submission of a new drug application to the Food and Drug Administration (FDA), and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have experienced significant setbacks in advanced clinical trials even after promising results in earlier trials. The Company may face the following risks in connection with clinical trials:

- a product candidate may not prove to be efficacious;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- results obtained in the later trial stage may not be consistent with the positive results obtained in earlier trials; and
- the trial results may be refused as unacceptable by FDA or other regulatory agencies.

To date, FDA has accepted Investigational New Drug (IND) applications for three of our seven product candidates. We are not allowed to conduct human clinical trials in the United States on other five product candidates until IND applications are accepted and there is no assurance that FDA will give approval for these applications. The commencement of clinical trials may be delayed for other reasons, including delays in:

- demonstrating sufficient safety to persuade regulatory authorities to allow a clinical trial to begin;
- reaching agreement on acceptable terms with prospective clinical trial institutions and clinical trial sites;
- production of a product candidate sufficient in quantity for clinical trials;
- obtaining approval for clinical trials from the institutional review board of a prospective clinical trial site; and
- obtaining sufficient patient enrollments (the required number is determined based on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial).

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of clinical trials or requests by them for supplemental information with respect to clinical trial results;
- failure to conduct clinical trials in compliance with regulatory requirements;
- lower than anticipated retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; or
- failure to provide the product candidate in sufficient quantity necessary for clinical trials, or lack of raw materials necessary for producing the product candidate, or defect in their quality.

Many of these factors described above may also ultimately lead to refusal of regulatory approval of a present or future product candidate. If the Company experiences delays in clinical trials, the commercial prospects for product candidates will be harmed and product revenues will be delayed.

2.6.1.5. *Failure to identify and license or acquire additional product candidates will hamper expansion of business.*

Since the Company's capacity and resources to develop new drugs are limited, its business is substantially dependent on acquisition of product candidates in the clinical trial stage or acquisition of license for them, which will be further developed into commercial products. The success of this strategy depends upon our ability to identify, select and acquire right product candidates. We have limited experience in identifying, negotiating and implementing acquisition of economically viable product candidates or acquisition of licenses for them, which is a lengthy and complex process. In addition, the market for acquiring product candidates or license for them is intensely competitive and many of our competitors have greater resources than the Company. We may not have capital resources necessary to consummate acquisitions of product candidates or licenses identified to fit the Company's strategy. Moreover, product candidate acquisitions involve numerous risks, including:

- difficulties in integrating the development program for the acquired product candidates into the existing operations;
- diversion of financial and management resources from existing operations;
- risks of entering new markets or new technology area;
- failure to generate sufficient revenues to offset acquisition costs; and
- delay that may result from implementation of unanticipated pre-clinical trials or other tests on the product candidate.

If the Company fails to identify and acquire additional product candidates or licenses for them, the Company will not be able to expand revenues from sales of new products.

2.6.1.6. *Failure to raise funds necessary for operations would prevent the Company from developing and commercializing product candidates.*

The Company has consumed substantial amounts of capital since its inception. From our inception (September 26, 2000) to December 31, 2004, we used $28.4 million in cash to fund our operating activities and fund net acquisitions of property and equipment. Although we believe the existing cash resources will be sufficient to fund our anticipated cash requirements through 2006, we will need significant additional financing in the future to fund our operations. The Company's future capital requirements depend on, and may increase significantly as a result of, many factors, including:

- progress in, and the costs of, our clinical trials;
- costs of securing manufacturing arrangements for clinical trials or commercial production;
- costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- costs of establishing or contracting for sales and marketing functions once regulatory approval is obtained for marketing of our product candidates.

Until significant recurring revenues are generated, the Company will satisfy future cash needs through strategic collaborations, private or public sales of its securities, debt financings or by licensing all or a portion of its product candidates. We do not have definite assurance that additional capital sources will be available on acceptable terms. We may not be able to procure necessary funds at all. If the Company fails to procure necessary funds, it may lose business opportunities that require financial commitments, and the Company may be forced to:

- terminate or delay clinical trials for one or more of product candidates;
- delay development of sales and marketing structures;

- curtail efforts to acquire new product candidates; or
- relinquish rights to the Company's technologies or product candidates.

2.6.1.7. *The Company may have to depend on strategic collaborations with independent parties for development and commercialization of selected product candidates and may not have control over a number of key elements relating to the development and commercialization of these product candidates.*

One of the key aspects of our strategy is to enter into collaborations with independent partners whereby we grant licenses for selected product candidates to larger pharmaceutical companies willing to conduct later-stage clinical trials and further develop and commercialize those products. To date, we have not entered into any collaborative arrangements with any independent partners and currently do not intend to do so until we have successfully completed Phase II clinical trial for one of our product candidates in the partnership program.

By entering into strategic collaborations, the Company may rely on partner companies for financial resources and for development, commercialization and pharmaceutical regulatory expertise.
Partners of the Company may fail to develop or effectively commercialize products by using product candidates of the Company:

- if they do not have sufficient resources or decide not to devote necessary resources due to internal constraints such as limited cash or human resources;
- if they decide to develop, independent from partnership agreement with us, a potential product that would compete with our product candidate; or
- if they fail to obtain necessary regulatory approvals.

The Company may not be able to enter into partnership agreements or, may have to accept agreements on unfavorable terms. The competition for locating partners is also very tense.

2.6.1.8. *Reliance on independent parties for clinical trials, data collection and analysis has a risk of costs or delay that may hamper successful development and commercialization of product candidates.*

Although the Company designs and manages its current clinical trials, it does not have the ability to conduct clinical trials for product candidates on its own. The Company will rely on independent research organizations, medical institutions, clinical investigators, and laboratories to conduct clinical trials, data collection and analysis on behalf of the Company. In the course of clinical development, we have contracted and will continue to contract with a number of research organizations, including, without limitation, MDS Pharma Services of Belfast, Northern Ireland; Pharmaceutical Research Associates, Inc. of Lenexa, Kansas; Fulcrum Pharma Developments, Inc. of Durham, North Carolina; and Quintiles, Inc. of Morrisville, North Carolina.

Clinical trials by any of these independent organizations may be delayed, suspended or terminated:

- if the independent organization fails to carry out its contractual duties or regulatory obligations or meet expected deadlines;
- if the independent organization needs to be replaced; or
- if the quality or accuracy of the data obtained by the independent organization is not reliable due to its failure to adhere to the clinical protocols designated by the Company or regulatory requirements or for other reasons.

Failure by third parties to perform their obligations under contract with the Company may result in increased development costs for the Company, delay in regulatory approval, or cancellation of our

commercializing plans for product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures.

2.6.1.9. *Product candidates of the Company may not gain acceptance among physicians, patients and the medical community, which would limit potential to generate revenues.*

Even if our product candidates are approved for commercial sale by FDA or other regulatory authorities, market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, profitability and growth will depend on a number of factors, including:

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our partners' sales and marketing strategy; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

If any product candidate developed by the Company does not provide a treatment that is as beneficial as the current standard treatment or otherwise does not provide patient benefit, that product is unlikely to be accepted by the market.

2.6.1.10. *The Company is dependent on the management team, particularly Takashi Kiyoizumi, M.D., Ph.D., a founder and chief executive officer, and Yuichi Iwaki, M.D., Ph.D., a founder and chairman of the board of directors. If we are unable to attract, retain and motivate these and other key management and scientific staff, our drug development programs may be delayed and we may be unable to successfully develop or commercialize our product candidates.*

The Company is dependent on the continued services of our executive officers and other key personnel, particularly Takashi Kiyoizumi, M.D., Ph.D., one of the founders and chief executive officer, and Yuichi Iwaki, M.D., Ph.D, one of the founders and the chairman of the board of directors. They have played an indispensable role in acquiring licenses for product candidates from Japanese drug companies and in securing financing from Japanese institutions. Because the Company has greatly relied and will rely on personal connections of these key executive managers in building relationships with licensors of product candidates or with prospective licensees for product candidates in our partnership program, the Company is particularly dependent upon continued employment of these executive managers with us. We are also substantially dependent on the continued services of our existing project managers because of the highly technical nature of our product development programs.

If new product candidates or licenses for new product candidates are acquired, the Company's success will depend on its ability to attract, retain and motivate highly qualified managers and scientists to manage the development of these product candidates. In particular, our drug development programs require employment and retention of experienced personnel having expertise in pharmaceutical development and regulatory affairs. In addition, we will need to hire additional personnel as we continue to expand our clinical development and other development activities. The Company has to compete with numerous companies and academic and other research institutions in recruiting experienced scientists and other technical and professional personnel. Competition for qualified workers is particularly intense in San Diego, California. Uncertainties, such as our short operating history, limited capital resource and the characteristic being a specialty pharmaceutical company still in the business development stage, may obstruct employment and retention of necessary workers, which may significantly impede the achievement of our development and commercialization goals.

Although we have employment agreements with key members of the management team, each of our employees, subject to applicable notice requirements, may terminate his or her employment at any time. We do not carry “key person” insurance covering members of senior management. If we lose any of our key management personnel, we may not be able to find suitable replacement and our business may be harmed as a result.

2.6.1.11. *Failure to establish sales and distribution system may hamper successful commercialization of the Company’s core product candidates.*

To date, the Company has not sold, marketed or distributed any pharmaceutical products. If the Company succeeds in developing and obtaining regulatory approvals for product candidates in its strategic core programs, the Company needs to establish sales, marketing and distribution systems. Developing an effective sales system and marketing force requires a significant amount of financial resources and time. We may fail to establish and manage a sales system, or fail to do so in a timely and cost-effective manner. The sales system we establish may not be capable of generating demand for our products. Although we intend to establish strategic collaboration with agents to market product candidates in our strategic core programs outside the United States, if we are unable to establish such collaborations, we may be required to directly market our strategic core product candidates outside the United States. In that event, we may need to build international sales and marketing systems having technical expertise and supporting distribution capability.

2.6.1.12. *Loss of service from independent scientific and clinical advisors may impair the progress of clinical trials and research and development efforts.*

The Company works with scientific and clinical advisors at academic and other institutions who are experts in the fields related to each of our drug development projects. They advise us on our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although these scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for the Company and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the clinical development of our product candidates. These advisors do not have any rights to publish data or information obtained in connection with their work for us without our consent and are obligated to keep confidential our proprietary information.

2.6.1.13. *The Company will need to increase the size of its organization. In expanding the business size, the Company may encounter difficulties that adversely affect the results of operations.*

The Company will need to expand and effectively manage its operations and facilities in order to promote drug development programs, achieve milestones under collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we intend to hire additional personnel in clinical development, pharmaceutical regulatory affairs and business development to further strengthen our core competencies. We also plan to hire additional managerial and administrative personnel to manage our business and daily operations as we continue to grow. In addition, we have to develop and strengthen sales, marketing and distribution systems for product candidates in our strategic core programs. The scope and timing of employment of these personnel is highly uncertain and remains subject to the success of our current product candidate development programs.

To manage the business growth, the Company needs to continue to improve its operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. Fulfillment of our public reporting obligations and other regulatory requirements in the United States and Japan places additional demands on our limited resources. We

may fail in the expansion of our operations and, accordingly, may not achieve our development and commercialization goals.

2.6.1.14. *Reliance on independent manufacturers may result in risk of delay in our clinical trials and market introduction of products, as well as increased costs.*

The Company has no manufacturing facilities of its own, and does do not intend to develop such facilities for product candidates for clinical trials or for the commercial purpose in the foreseeable future. We have entered into contracts with independent manufacturers for the production of, in collaboration with us, our product candidates for clinical trials. If any of these contracts are terminated, or any of these manufacturers fails to manufacture product candidates, we believe that there are other competitive manufacturers available. However, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate such delay or costs with certainty. To date, these manufacturers have met the requirements of our programs.

Our manufacturers are required to operate in accordance with FDA-mandated current good manufacturing practices (GMPs). Failure by any of our contract manufacturers to establish and follow current GMPs and to document their adherence to such practices may lead to significant delay in clinical trials or in obtaining regulatory approval for product candidates or the ultimate launch of our products into the market. In addition, changing manufacturers is difficult. For example, a new manufacturer must be validated regarding the compliance of its manufacturing processes and procedures with current GMPs, which may be costly and time-consuming. Failure by a contract manufacturer or by the Company to comply with applicable regulations could result in sanctions being imposed on the Company, including fines, injunctions, civil penalties, refusal, delay, suspension or revocation by the government of pre-market approval of drugs, seizures or recalls of products, operating restrictions and criminal prosecutions.

2.6.2. **Risks related to our intellectual property**

2.6.2.1. *Our ability to compete may decline if we do not adequately protect our proprietary rights.*

To date, we have obtained licensed rights under ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending non-U.S. patents corresponding to these U.S. patents. In addition to these licensed rights, we hold three U.S. patent applications relating to MN-001 and its metabolite, MN-002.

Patent protection of our product candidates and technology involves complex legal and factual questions. In general, our license agreements give us the right, but not the obligation, to enforce our patent rights. We cannot be certain that any of the patents or patent applications owned by us or our licensors related to our product candidates and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates;
- obtain and maintain any required or desirable licenses to use certain third-party technologies that may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellecutal property or proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

The degree to which we will be able to protect our proprietary rights in future is uncertain. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or unenforceable under the laws of the U.S. or other countries;
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully; or
- we may not develop additional proprietary technologies that are patentable.

Proprietary trade secrets and unpatented know-how may also prove to be very important to our future research and development activities. However, we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps – including entering into confidentiality agreements with all of our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors – to protect our trade secrets and unpatented know-how and keep them secret. We also typically obtain agreements from these parties stipulating that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

2.6.2.2. *A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.*

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. There are many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, we may have to pay significant damages. A patentee could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce the patents granted to our company, to protect our trade secrets, and to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. When necessary, our company may hire persons with scientific expertise employed at other companies engaged in one or more areas of activity similar to those in which we are involved. Again, we may be subject to claims that we have inappropriately used the trade secrets or other proprietary information of third parties. Becoming involved in litigation could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our partners could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a third party’s patent rights;

- injunctions or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- we or our partners not being able to enter into license arrangements on commercially acceptable terms or indeed not being able to enter into license arrangements at all; and
- significant cost and expenses, as well as distraction of our management from our business operations.

As a result, we could be prevented from commercializing current or future products.

2.6.3. **Risks Related to Our Industry**

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

We, our collaborators, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Our product candidates cannot be marketed in the United States until the FDA has approved the product candidates. It is possible that we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial managerial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products, and may require post-approval testing, including additional research and development and clinical trials. 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 have a material adverse effect on our ability to generate revenues from the particular product candidate. In addition, both before and after regulatory approval, we, our collaborators, and our product candidates are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution, and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our collaborators, and our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. In order to market our products outside of the United States, we and our strategic collaborators and licensees must satisfy and comply with numerous and varying regulatory requirements in other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval processes in other countries may include all of the risks detailed above regarding FDA approval in the United States. Regulatory approval of a pharmaceutical product in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval of that pharmaceutical product in one country may negatively impact the regulatory processes in others. Failure or delay in obtaining, or withdrawal of applications for, regulatory approval of a pharmaceutical product in countries other than the US could therefore negatively impact the regulatory processes as described above with regard to approval from the FDA in the US. There is also the risk that the product candidate may not be approved for all the indicated disorders listed in our application, which would limit the uses of our product and adversely impact our potential royalties and product sales. Such conditional approval could limit the indicated uses of the products to be sold and/or require expensive post-marketing surveillance studies. If we fail to comply with the regulatory requirements for pharmaceutical products in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in receiving or failure to receive approval for a product, suspension of operations or withdrawal of regulatory approval, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution.

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

Competition in the pharmaceutical industry is intense and is expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in both the United States and other countries. Some of these competitors have products or are pursuing the development of products that target the same diseases and conditions that are the focus of our own drug development programs. Our competitors could have products that are in advanced development and may succeed in developing drugs that are more effective, safer and 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 drugs that we may develop. In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms, biological responses, and side effects. Many of our competitors have substantially greater capital and research and development resources, 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 established pharmaceutical companies.

2.6.3.3 *Rapid technological change could make our products obsolete*.

Biopharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. As a result, there is significant risk that our current product candidates may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidates are rendered obsolete by advancements in biopharmaceutical technologies, our future prospects will suffer.

2.6.3.4 *Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.*

Developing and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products. Consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or third parties selling these products may seek contribution from us if they incur any losses or expenses related to such claims. We currently have product liability insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time. We will, however, need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or one of our collaborators develop. Product liability claims could have a material adverse effect on our operations and business results. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one or more of our drug products.

2.6.3.5 *Health care reform measures could adversely affect our business.*

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in other jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing health care systems. For example, the

pricing of prescription drugs is subject to government control in some countries other than the United States, and we expect proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is the current discussion of drug reimportation into the United States. In 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs are being sold at lower prices. Although the Secretary of Health and Human Services has refused to implement this directive, the House of Representatives passed a similar bill in July 2003 that does not require action by the Secretary of Health and Human Services. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or our collaborators receive for our product candidates once they are approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic collaborations or licenses.

2.7 **Fundamental policy on corporate governance and implementation of relevant measures**

2.7.1 **Basic Policy for Corporate Governance**

In order to enhance enterprise value continuously, the company recognizes the significance to ensure the transparency of management and to strengthen the control of management. To this end, the company strives to improve corporate governance system.

2.7.2 **The implementation of corporate governance**

2.7.2.1 *Corporate Organization*

Board of Directors

The board of directors of the Company currently consists of five directors. All directors were elected to hold office until their successors are elected and qualified or until their death, resignation, disqualification or removal, whichever earlier. Effective upon the date of this document, the office terms of directors are divided into three classes:

- Class I: the term will expire at the annual meeting of stockholders to be held in 2005;
- Class II: the term will expire at the annul meeting of stockholders to be held in 2006; and
- Class III: the term will expire at the annual meeting of stockholders to be held in 2007.

As of the date hereof, Class I consists of Messrs. Kiyoizumi and Nagao, Class II consist of Drs. Vapnek and Iwaki and Class III consists of Dr. Prendergast. Messrs. Prendergast, Vapnek and Nagao are independent directors as defined by Rule 4200(a)(15) of the National Association of Securities Dealers Marketplace Rules of the United States. At each annual meeting of stockholders after the initial classification, the successors to directors whose terms then expire will serve from the time of election and qualification until the third annual meeting following the election and until their successors are duly elected and qualified. The authorized number of directors may be changed by resolution of the board. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of all directors. Vacancies on the board may be filled by resolution of the board of directors. We believe this classification of directorship is effective for delaying or preventing changes in control or management of the Company.

Board Committees

The board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. As of the date of this document, all of committee members are independent directors under the rules of SEC and the Nasdaq Stock Market. Although the Company is not currently subject to the rules of the U.S. Nasdaq Stock Market, the Company intends to comply with Nasdaq's rules regarding board independence and corporate governance while it is listed on the Hercules market of the Osaka Securities Exchange.

Audit Committee. As of the date of this document, the audit committee consists of Messrs. Prendergast, Vapnek and Nagao, with Dr. Prendergast serving as the chair of the committee. The audit committee provides assistance to the board of directors in fulfilling its legal and fiduciary obligations in matters involving accounting, auditing, financial reporting, internal control and legal compliance functions. The audit committee approves the services performed by independent accountants and reviews their reports regarding the Company's accounting practices and internal accounting controls. The audit committee is responsible for the appointment, compensation, retention and oversight of independent accountants hired by the Company and ensures that the accountants are independent of the management team. Pursuant to applicable SEC rules, the Company is required to disclose whether it has an "audit committee financial expert" serving on the audit committee. Each member of the audit committee has been selected by the board of directors based on its determination that the member is fully qualified to monitor the performance of the management team, the public disclosure of the Company's financial condition and operational results, internal controls over financial reporting and the performance of independent auditors, as well as to analyze and evaluate financial statements. However, the board of directors believes that none of the audit committee members meets all of the criteria specified in the SEC rules to qualify as an "audit committee financial expert." The financial statements of the Company are not very complex and the Company has not earned significant revenues because it is still in the early stage of business development. Considering the current situation of the Company, the board of directors determined that it is appropriate for the audit committee not to have an "audit committee financial expert." The board of directors determined that the financial sophistication of the current audit committee members, as evidenced by their previous and current financial and business experience, is sufficient for the audit committee to ensure the integrity of financial statements and to fully and completely fulfill its role under the audit committee charter. In addition, the audit committee is authorized to retain, at the expense of the Company, special legal, accounting or other advisors or consultants whenever it deems necessary or appropriate.

Compensation Committee As of the date of this document, the compensation committee consists of Messrs. Prendergast, Vapnek and Nagao, each of whom is a non-management member of the board of directors, with Dr. Prendergast serving as the chair of the committee. The compensation committee determines general compensation policy and compensation provided to the directors and officers of the Company. The compensation committee also reviews and determines bonuses for officers and other employees. In addition, the compensation committee reviews and determines equity based compensation programs for directors, officers, employees and consultants and administers stock option plans and employee stock purchase plan of the Company.

Nominating and Corporate Governance Committee. As of the date of this document, the nominating and corporate governance committee consists of Messrs. Prendergast, Vapnek and Nagao, with Dr. Prendergast serving as the chair of the committee. The nominating and corporate governance committee is responsible for making recommendations to the board of directors regarding candidates for directorships and the size and composition of the board and for overseeing corporate governance guidelines, and reporting and making recommendations to the board concerning corporate governance matters.

2.7.2.2 The system for internal control and risk management

During fiscal year 2005, the company will review and improve the corporate system for internal control and risk management to comply with Section 404 of the Sarbanes-Oxley Act.

2.7.2.3 Directors' compensation

The Company intends to pay to non-employee board members, the following compensations related to their service on the board, provided that they should have attended at least 80% of the board meetings and applicable committee meetings:

- an initial compensation of $20,000 for accepting the office of director; and
- an annual compensation of $20,000.

In the event that a board member attends less than 80% of such meetings, the board member will receive 25% of the cash compensation he or she would otherwise receive. In addition, non-employee and non-consultant directors, other than Mr. Nagao, will receive nondiscretionary, automatic grants of non-qualified stock options. A non-employee director is granted automatically an initial option to purchase 10,000 shares upon first becoming a member of the board of directors. The initial option is fully vested at the time of grant. Immediately after the annual general meeting of stockholders each year, each non-employee director, other than Mr. Nagao, will be granted automatically a non-qualified option to purchase 10,000 common shares of the Company, provided the director has served on the board for at least six months. Each annual option will vest and become fully exercisable six months after the date of the grant. Options granted to non-employee directors will have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant and will become fully vested immediately if the control over the Company has changed. The Company reimburses directors for reasonable expenses incurred by them for attending board and committee meetings.

2.7.2.3.1 No Compensation Committee Interlocks and Insider Participation

None of the compensation committee members at any time has served or is serving as an officer or employee of the Company. No interlocking relationship exists, or has existed in the past, between the board or compensation committee of the Company and the board or compensation committee of any other company.

2.7.2.3.2 Executive Compensation

The table below shows the aggregate amount of all compensation, bonuses and salaries earned by executive officers whose salary and bonus exceeded $100,000 for services rendered in all capacities to the Company during 2004. Compensation shown in this table does not include medical, group life insurance or other benefits which are generally available to all salaried employees of the Company.

Summary Compensation Table

	Aggregated Annual Compensation			Long-term Incentive Compensation
	Salary	Bonus	Other Compensation	Stock Options (number of shares)
2004	1,157,565	434,400	41,752	730,000

2.7.2.3.3 Stock Options

2.7.2.3.4.1 Aggregate Option Exercises in 2004

No options were exercised during the fiscal year ended December 31, 2004.

2.7.2.3.4.2 Options Granted in 2004

The following table shows a summary of options to purchase the Company's common shares granted to the executive officers and non-employee directors during 2004. The exercise price per share of each option was determined by the board of directors at fair market value on the date of the grant.

Name	2004 Option Grants
Executive Officers[1]	
Brian Anderson	200,000
Richard E. Gammans, Ph.D.	160,000
Kenneth W. Locke, Ph.D.	120,000
Mark Lotz	120,000
Joji Suzuki, M.D., Ph.D.	130,000
Non-Employee Directors[2]	
John K. A. Prendergast, Ph.D.	10,000
Daniel Vapnek, Ph.D.	10,000

(1) 25% of all options granted to executive officers will vest on the first anniversary from the grant date, and the remaining 75% vests equally every month over a period of three years commencing on the first anniversary of the grant date.

(2) All options granted to non-employee directors are fully vested upon grant.

2.7.2.3.4.3 Stock Plans

2000 General Stock Incentive Plan

In September 2000, we adopted our 2000 General Stock Incentive Plan. The plan is administered by our board of directors although the board may delegate the authority to administer the plan to a committee of directors or one or more officers, provided, however, that committee functions may not be delegated to officers to the extent that option grants relate to persons who are subject to the reporting requirements of Section 16 of the Securities Exchange Act of 1934, as amended and including subsequent amendments, (hereafter referred to as the Exchange Act). A total of 2,000,000 shares of common stock are authorized for issuance under the 2000 General Stock Incentive Plan.

Shares subject to stock options that have expired, been cancelled or have otherwise terminated without having been exercised in full will again become available for grant. The 2000 General Stock Incentive Plan permits the grant of options to our directors, officers, other employees and consultants. Options may be either incentive stock options to employees within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended or nonstatutory stock options. The maximum term of options granted under the plan is ten years. Except in specified circumstances, no person may be granted more than 600,000 shares of common stock in 12-month period. Options granted under the 2000 General Stock Incentive Plan are generally nontransferable and vest at the rate determined by the administrator of the plan. Options granted under the 2000 General Stock Option Plan vest based on periods determined by our board of directors which has been four years for employees and other option recipients.

The 2000 General Stock Incentive Plan provides that in the event of a recapitalization, stock split or similar transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under

the plan. If we are involved in a merger, consolidation or other reorganization, outstanding options granted under the 2000 General Stock Incentive Plan will be subject to the agreement of merger or reorganization.

As of December 31, 2004, options to purchase a total of 1,550,000 shares of common stock were outstanding under the 2000 General Stock Incentive Plan at a weighted average exercise price of $1.00 per share. No additional options will be issued under the 2000 General Stock Incentive Plan and future use of this plan has been terminated effective as of the consummation of the Company's recent public offering.

2004 Stock Incentive Plan

General. The 2004 Stock Incentive Plan is intended to serve as the successor program to our 2000 General Stock Incentive Plan. The 2004 Stock Incentive Plan was adopted by our board of directors in November 2004 and approved by out stockholders on December 21, 2004, and became effective upon the completion of the Company's initial public offering.

Administration. The 2004 Stock Incentive Plan will be administered by our compensation committee. Our board of directors may also appoint one or more separate committees to administer the 2004 Stock Incentive Plan with respect to employees who are not considered officers or directors under Section 16 of the Exchange Act. The 2004 Stock Incentive Plan provides for the grant of (i) options to purchase shares of common stock, (ii) restricted stock, (iii) stock appreciation rights and (iv) stock units. Incentive stock options may only be granted to new employees. Nonstatutory stock options and other stock-based awards may be granted to employees, non-employee directors, advisors and consultants.

The board of directors will be able to amend or modify the 2004 Stock Incentive Plan at any time, with stockholder approval, if required.

Authorized Shares. 20,300,000 shares of common stock have been authorized for issuance under the 2004 Stock Incentive Plan. However, no participant in the 2004 Stock Incentive Plan can receive option grants or stock appreciation rights for more than 2,030,000 shares total in any calendar year. The number of shares reserved for issuance under the 2004 Stock Incentive Plan will be increased on the first day of each of our fiscal years from 2006 through 2014, with the first such increase occurring on January 1, 2006, by the lesser of:

- 1,000,000 shares,
- 3% of our outstanding common stock on the last day of the immediately preceding fiscal year; or
- the number of shares determined by our board of directors.

Plan Features

Under the 2004 Stock Incentive Plan:

- We expect that options granted to optionees other than non-employee directors will generally vest as to 25% of the shares one year after the date of grant and as to 1/48 of the shares each month thereafter.
- Nondiscretionary, automatic grants of nonstatutory stock options will be made to non-employee directors. A non-employee director will be granted automatically, unless such director waives his or her right to such grant, an initial option to purchase 10,000 shares upon first becoming a member of our board of directors. The initial option vests and becomes exercisable at the time of grant. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director will be automatically granted a nonstatutory option to purchase 10,000 shares of our common stock, provided that the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the date which is six months after the date of grant. The options granted to non-employee directors will have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant, and will become fully vested if we are subject to a change on control.

- Generally, if we merge or engage in a similar type of transaction with or into another corporation, we may accelerate the vesting or exercisability of outstanding options, restricted stock, stock appreciation rights or stock units which were granted under the plan or terminate through settlement of the full value in cash or cash equivalents of any unexercised options, restricted stock, stock appreciation rights or stock units which were granted under the plan unless they are assumed or substituted for by any surviving entity or a parent or subsidiary of the surviving entity.
- The plan terminates ten years after its initial adoption by the board of directors, unless earlier terminated by the board of directors. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law. Any amendment or termination may not impair the rights of holders of outstanding awards without their consent.

2.7.2.3.5. *Limitation of Liability and Indemnification Matters*

Our restated certificate of incorporation limits the liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for:

- any breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our restated certificate of incorporation and bylaws provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. Our restated certificate of incorporation and bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in such capacity, regardless of whether the bylaws would permit indemnification.

We have entered into agreements to indemnify each of our directors and executive officers, in addition to the indemnification provided for in our restated certificate of incorporation and bylaws. In addition, we maintain directors' and officers' liability insurance. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

3. Operating Results and Financial Condition

3.1 Operating Results

Operating Results	Year ended December 31, 2004	Year ended December 31, 2003	Change from previous year
Revenues	490,282	—	490,282
Operating Loss	(48,612,386)	(6,261,103)	(42,351,283)
Net Loss	(48,272,603)	(6,209,130)	(42,063,473)

3.1.1 *Overview*

Despite a sharp rise in oil prices, a burgeoning fiscal deficit, a weaker dollar and other destabilizing factors, the US economy continued to enjoy relatively stable growth. However, moderate economic

expansion generated only modest growth in the pharmaceutical industry's major markets and, according to the market research firm IMS Health, the growth rate for the US pharmaceuticals market dropped below double digits in 2004 for the first time since 1995. Both the general public and regulatory authorities now demand more rigorous disclosure from the pharmaceutical industry on drug product safety, and the pharmaceutical industry will continue to face a difficult business environment.

Given these circumstances, we actively addressed three business challenges this term. The first was continued expansion of our pipelines for promising product candidates. MN-221 (for the treatment of premature labor), MN-305 (for the treatment of generalized anxiety disorder), MN-166 (for the treatment of multiple sclerosis), and MN-246 (for the treatment of urinary incontinence) were newly added to the development portfolio during this term. The second challenge was further progress in our development programs via a dual pathway: strategic core programs and partnering programs. We submitted an application to begin clinical testing of the new drug MN-221 as well as an application to begin clinical testing and Phase 1 clinical trials of the new anticancer drug MN-029 as part of our strategic core programs this term, while in partnering programs we submitted applications to begin clinical testing of the new MN-001 for bronchial asthma and to commence latter-stage Phase 2 clinical testing for MN-305. The third challenge tackled was enhancement of our management team. Our company management was bolstered this term by the addition of four operating officers and the appointment of three new independent directors.

Revenues

Our revenues totaled $0.5 million for the year ended December 31, 2004 from development management services performed under two master services agreements. We had no revenue during the same period in 2003.

Research and Development

Research and development expenses increased to $11.2 million for the year ended December 31, 2004 from $4.7 million for the year ended December 31, 2003. This increase primarily was due to:

- an increase of $3.6 million in our strategic core programs as a result of $1.1 million of clinical trial and related costs and $2.5 million of milestone, licensing and other costs;
- an increase of $2.7 million in our partnering programs as a result of $1.0 million of clinical trial and related costs and $1.7 million of licensing and other costs;
- a decrease of $0.9 million in our SOCC program as a result of $0.7 million of reduced pre-clinical development when we redirected our resources to our strategic core and partnering programs and $0.2 million of other costs; and
- an increase of $1.3 million in unallocated expenses as a result of increased salaries and related personnel costs due to increased research and development staff.

General and Administrative

General and administrative expenses increased to $3.2 million for the year ended December 31, 2004 from $1.5 million for the year ended December 31, 2003. This increase primarily was due to $0.9 million of salaries and related costs as we expanded our general and administrative functions to support our operations, $0.4 million of legal fees, other professional fees and consulting fees and expenses paid to the chairman of our board of directors and $0.4 million of other expenses.

Stock-Based Compensation

Stock-based compensation expenses totaled $34.3 million for the year ended December 31, 2004 due to the issuance of warrants at exercise prices below the estimated fair value of our common stock and the

amortization of deferred stock-based compensation. We had no issuances of options or warrants during the comparable period in 2003 that required us to record stock-based compensation expenses.

Operating Loss and Net Loss

Operating loss was $48.6 million and net loss was $48.3 million for the year ended December 31, 2004. Both operating loss and net loss increased by $42.4 million and $42.1 million, respectively, over the prior year for the reasons noted above.

3. 2 Financial Conditions

3.2.1 Assets, Liabilities and Stockholders' Equity

Total assets increased to $53.8 million at December 31, 2004 from $5.6 million at December 31, 2003. Cash and cash equivalents and marketable securities available-for-sale increased by $45.3 million due to those factors noted in Section 3.2.2. Other assets increased by $2.2 million as a result of deferred offering costs related to the Company's initial public offering. Accrued expenses increased to $1.6 million at December 31, 2004 from $0.3 million at December 31, 2003 primarily due to costs accrued related to the Company's initial public offering. Redeemable convertible preferred stock increased by $43.5 million as a result of the sale of Series C redeemable convertible preferred stock in September 2004. Stockholders' equity increased to $7.7 million at December 31, 2004 from $4.6 million at December 31, 2003 as a result of the sale of $17.2 million of Series B preferred stock offset by the net loss for the year ended December 31, 2004 (excluding non-cash stock-based compensation).

3.2.2 *Cash Flows*

	Year ended December 31, 2004	Year ended December 31, 2003	Change from previous year
Net cash used in operating activities	(13,546,476)	(5,931,250)	(7,615,226)
Net cash used in investing activities	(11,071,235)	(1,065,716)	(10,005,519)
Net cash provided by financing activities	59,178,340	9,956,547	49,221,793
Cash and cash equivalents, beginning of period	4,240,699	1,281,118	2,959,581
Cash and cash equivalents, end of period	38,801,328	4,240,699	34,560,629

As of December 31, 2004, we had $50.8 million in cash and investments as compared to $5.5 million as of December 31, 2003, an increase of $45.3 million. This increase primarily resulted from completion of the sale of our Series B and Series C preferred stock. Net cash used in operating activities amounted to $13.5 million for the year ended December 31, 2004, primarily reflecting the net loss occurring for this period of $48.3 million, offset by non-cash charges for stock-based compensation of $34.3 million. Net cash used in investing activities for the year ended December 31, 2004 consisted of $0.3 million of capital equipment purchases exclusive of $10.8 million for the purchase of investments. Net cash provided by financing activities amounted to $59.2 million for the year ended December 31, 2004, primarily reflecting the sale of Series B and Series C preferred stock.

	Year Ended December 31, 2004
Stockholders' Equity Ratio	14.3%
Capital Adequacy Ratio on Market Price Basis	—
Years for Amortization	—
Interest Coverage Ratio	—

4. Forecast of Performance Results for Next Term (Fiscal Year ended December, 2005)

	Fiscal Year Ending December 31, 2005 (forecast)	Incremental Change from Fiscal Year Ended December 31, 2004 (actual)	
Revenue	750,000	259,718	53%
Operating Loss	(40,900,000)	(7,712,386)	(—%)
Net Loss	(37,700,000)	(10,572,603)	(—%)

Note: Our independent auditors have not compiled or been involved in the preparation of the forecasted results for 2005. Accordingly, they assume no responsibility for the accuracy or presentation of this information. All comparisons are made against year ended December 31, 2004 actual results.

We expect a 53% increase in revenue in the year ending December 31, 2005 over the $0.5 million in 2004 due to increased activity under our development management contracts. We also expect operating loss in 2005 will decrease by $7.7 million from $48.6 million in 2004. We anticipate a continued increase in research and development expenditures in 2005 over 2004 due to the expansion and progress of our portfolio of product candidates. This increase will be offset, however, by a decrease of stock-based compensation expense because we will not incur further non-cash charges related to our founders' warrants in 2005. We further expect that net losses in 2005 will decrease by $10.6 million from $48.3 million in 2004. In addition to the reasons for the decrease of operating loss in 2005 from 2004, we anticipate an increase in interest income in 2005 due to the increase of cash and cash equivalents and investments in 2005 from 2004.

5. Individual Financial Statements

5.1 Balance Sheet

Description	Dec. 31, 2004	Component Ratio	Dec. 31, 2003	Component Ratio	Change from prior year
Assets					
Current Assets:					
Cash and cash equivalents*	$ 38,801,328		$ 4,240,699		$ 34,560,629
Marketable securities available-for-sale*	12,000,000		1,250,000		10,750,000
Prepaid expenses and other current assets	487,576		108,360		379,216
Total Current Assets	51,288,904	95.4%	5,599,059	99.4%	45,689,845
Property and equipment, net*	308,187		32,250		275,937
Other assets*	2,171,504		—		2,171,504
Total Assets	$ 53,768,595	100.0%	$ 5,631,309	100.0%	$ 48,137,286
Liabilities and stockholders' equity					
Current Liabilities:					
Accounts payable	$ 469,798		$ 329,328		$ 140,470
Accrued expenses	1,552,622		294,500		1,258,122
Accrued payroll and related expenses	562,656		137,599		425,057
Total Current Liabilities	2,585,076	4.8%	761,427	13.5%	1,823,649
Deferred Rent	31,321		—		31,321
Advances received for the sale of convertible preferred stock	—		300,000		(300,000)
Redeemable Convertible Preferred Stock, $0.01 par value*	43,483,076	80.9%	—		43,483,076
Number of authorized shares:					
27,667,856 shares as of December 31, 2004					
No shares as of December 31, 2003					
Number of issued shares:					
27,667,856 shares as of December 31, 2004					
No shares as of December 31, 2003					
Stockholders' Equity					
Convertible Preferred Stock, $0.01 par value	12,912		11,075		1,837
Number of authorized shares:					
1,291,150 shares as of December 31, 2004					
3,000,000 shares as of December 31, 2003					
Number of issued shares:					
1,291,150 shares as of December 31, 2004					
1,107,500 shares as of December 31, 2003					
Common Stock, $0.001 par value	500		500		—
Number of authorized shares:					
83,000,000 shares as of December 31, 2004					
80,000,000 shares as of December 31, 2003					
Number of issued shares:					
500,000 shares as of December 31, 2004					
500,000 shares as of December 31, 2003					
Additional paid-in capital	103,603,132		19,694,972		83,908,160
Deferred Employee Stock-Based Compensation*	(1,194,721)		—		(1,194,721)
Deficit accumulated during the development stage	(94,752,701)		(15,136,665)		(79,616,036)
Total Stockholders' Equity	7,669,122	14.3%	4,569,882	81.2%	3,099,240
Total Liabilities and Stockholders' Equity	$ 53,768,595	100.0%	$ 5,631,309	100.0%	$ 48,137,286

* Please see Notes to Financial Statements below.

5.2 Profit and Loss Statement

Description	Year Ended Dec. 31, 2004	%	Year Ended Dec. 31, 2003	%	Change from prior year
Revenues	$ 490,282	100.0	$ —		$ 490,282
Operating Expenses					
Cost of revenues	437,582	89.3	—		437,582
Research and development*	11,210,285	2,286.5	4,723,158		6,487,127
General and administrative	3,160,306	644.6	1,537,945		1,622,361
Amortization of employee stock-based compensation and founders' warrants:*					
Research and development	106,770		—		106,770
General and administrative	34,187,725		—		34,187,725
Total Operating Expenses	49,102,668	10,015.2	6,261,103		42,841,565
Operating Loss	(48,612,386)		(6,261,103)		(42,351,283)
Other Income, net	339,783		51,973		287,810
Net Loss	(48,272,603)		(6,209,130)		(42,063,473)
Accretion to redemption value of redeemable convertible preferred stock	(78,756)		—		(78,756)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	(31,264,677)		—		(31,264,677)
Net loss applicable to common stockholders	$ (79,616,036)		$ (6,209,130)		$ (73,406,906)
Basic and diluted net loss per share	$ (159.23)		$ (12.42)		
Shares used to compute basic and diluted net loss per share	500,000		500,000		
Pro forma net loss per common share assuming conversion of preferred stock, basic and diluted (unaudited)	$ (1.85)				
Shares used in computing pro forma net loss per common share assuming conversion of preferred stock, basic and diluted (unaudited)	42,943,281				

* Please see Notes to Financial Statements below.

5.3 Deficit Accumulated During the Development Stage

	Year Ended Dec. 31, 2004	Year Ended Dec. 31, 2003
Beginning Deficit Accumulated During the Development Stage	$ (15,136,665)	$ (8,927,535)
Net loss	(48,272,603)	(6,209,130)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	(31,264,677)	—
Accretion to redemption value of redeemable convertible preferred stock	(78,756)	—
Ending Deficit Accumulated During the Development Stage	$ (94,752,701)	$ (15,136,665)

5.4 Cash Flow Statement

Description	Year ended December 31, 2004	Year ended December 31, 2003	Decrease (Increase)
Operating activities:			
Net loss	$ (48,272,603)	$ (6,209,130)	$ (42,063,473)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	34,294,495	—	34,294,495
Depreciation and amortization	45,298	29,872	15,426
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(379,216)	(49,394)	(329,822)
Accounts payable, accrued expenses and deferred rent	340,493	444,412	(103,919)
Due to affiliate	—	(265,466)	265,466
Accrued compensation and related expenses	425,057	118,456	306,601
Cash flows from operating activities	(13,546,476)	(5,931,250)	(7,615,226)
Purchases of marketable securities available-for-sale	(10,750,000)	(1,250,000)	(9,500,000)
Acquisitions of property and equipment	(321,235)	(10,537)	(310,698)
Proceeds from sale of property and equipment	—	194,821	(194,821)
Net cash used in investing activities	(11,071,235)	(1,065,716)	(10,005,519)
Payment of IPO issuance costs	(1,082,084)	—	(1,082,084)
Sales of preferred stock, net of issuance costs	60,560,424	9,656,547	50,903,877
Advances received for the sale of convertible preferred stock	(300,000)	300,000	(600,000)
Net cash provided by financing activities	59,178,340	9,956,547	49,221,793
Net increase in cash and cash equivalents	34,560,629	2,959,581	31,601,048
Cash and cash equivalents, beginning of period	4,240,699	1,281,118	2,959,581
Cash and cash equivalents, end of period	$ 38,801,328	$ 4,240,699	$ 34,560,629

5.5 Important Basic Matters for Compiling Financial Statements

5.5.1 Main Accounting Policy

5.5.1.1 *Valuation of Securities*

Investments with an original maturity of more than three months are considered short-term investments and have been classified by management as marketable securities available-for-sale. Such investments consist mainly of municipal auction rate securities and are carried at fair value with unrealized gains and losses, if any, included as a separate component of stockholders' equity.

5.5.1.2 *Depreciation Method of Important Tangible Fixed Assets*

The Company's important tangible fixed assets, which consist of annexed structures of buildings and fixtures, are stated at cost and depreciated using the straight-line method over the estimated useful lives of the related assets. The useful life for fixtures is five years, and annexed structures of buildings are amortized over the lesser of the useful life or the term of the lease. The Company's current lease will expire in 2008.

5.5.1.3 *Disposition Method of Deferred Assets*

5.5.1.3.1 *Corporate Income Tax*

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, *Accounting for Income Taxes*, a deferred tax asset or liability is determined based on the difference between the financial statement and the tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized after offsetting.

5.5.1.3.2 *Expenses for Issuance of New Stock*

Costs associated with the initial public offering will be accounted for as a reduction to the gross proceeds of the offering in the statement of stockholders' equity at the completion of the offering. Prior to completion of the offering, costs associated therewith are capitalized as other assets.

5.5.1.4 *Computation Standard for Assets and Liabilities in Foreign Currencies into Home Currency*

Assets and liabilities of foreign operations where the functional currency is other than the U.S. dollar are translated at fiscal year-end rates of exchange, and the related revenue and expense amounts are translated at the average rates of exchange during the fiscal year.

5.5.1.5 *Disposition Method of Lease Transaction*

The Company leases its facilities under operating leases. The minimum annual rent on the Company's facilities is subject to increases based on stated rental adjustment terms of certain leases, taxes, insurance and operating costs. For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the leases. Accordingly, rent expense recognized in excess of rent paid is reflected as deferred rent.

5.5.1.6 *Recording Standard of Reserves*

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts

of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

5.5.1.7 *Recording Standard of Revenue and Expenses*

5.5.1.7.1 *Revenue Recognition*

In connection with the management of clinical trials, the Company pays, on behalf of its customers, fees to responsible doctors for clinical trials and other pass-through costs for which it is reimbursed at cost, without mark-up or profit. In addition, the Company charges management fees based on negotiated hourly rates pursuant to master services agreements with Asahi Kasei Pharma Corporation and Argenes Inc. The Company recognizes management fees based on actual hours worked and recognizes pass-through expenses as revenue when the related liability is incurred in accordance with Emerging Issues Task Force ("EITF") Rule No. 01-14, *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred*. EITF No. 01-14 requires reimbursable pass-through expenses incurred to be characterized as revenue in the profit and loss statement. Pass-through costs represent the majority of cost of revenues during the year ended December 31, 2004.

5.5.1.7.2 *Research and Development Expenses*

Research and development expenses consist of costs incurred to further the Company's research and development activities and include salaries and related employee benefits, costs associated with clinical trials and non-clinical activities such as toxicology testing and pharmaceutical activities and research-related overhead expenses. They also include fees for external service providers to conduct particular research and development activities and contract research organizations to conduct clinical trials on behalf of the Company. Research and development expenses also include fees for licensed technology for which technological feasibility has not been established and there are no alternative uses. Research and development costs are expensed as incurred.

5.5.1.7.3 *Stock-Based Compensation*

The Company has elected to follow Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employee*s, and related interpretations in accounting for its employee stock options and warrants as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB Opinion No. 25, if the exercise price of the Company's employee stock options or warrants is not less than the fair value of the underlying stock on the date of grant, no compensation expense is recognized. In determining the fair value of the common stock, the Board of Directors considered, among other factors, (i) the advancement of the Company's technology, (ii) the Company's financial position and (iii) the fair value of the Company's common stock or preferred stock as determined in arm's-length transactions.

5.5.1.7.4 *Comprehensive Income*

The Company has adopted SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, including foreign currency translation adjustments and unrealized gains and losses on investments, shall be reported, net of their related tax effect, to arrive at comprehensive income.

5.5.1.8 *Cash and Cash Equivalents as used in the Statement of Cash Flows*

Cash and cash equivalents consist of cash and other highly liquid investments with original maturities of three months or less from the date of purchase.

5.5.1.9 *Impairment of Fixed Assets*

The Company reviews long-lived assets, including fixed assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. Impairment, if any, is assessed using discounted cash flows.

5.5.1.10 *Differences in Accounting Principles and Practice between the United States of America and Japan*

The Company has prepared the financials included in this document in accordance with the accounting principles generally accepted in the U.S. (U.S. Accounting Principles). Therefore, these financials are different in accounting principles from those compiled in accordance with the accounting principles generally accepted in Japan (Japanese Accounting Principles). The main differences between the U.S. Accounting Principles and the Japanese Accounting Principles are as follows:

5.5.1.10.1 *Impairment of Long-Lived Assets and Those to be Disposed*

According to the U.S. Accounting Principles, when any events indicate that the carrying amount of the assets may not be recoverable for retained and utilized long-lived assets and specific recognizable intangible assets, the Company must study whether the impairment of values occurs or not. If any indication of impairment is recognized, the Company has to decide whether the total amount of the estimated undiscounted future cash flows expected to result from the subject asset is less than its carrying amount. If yes, the Company recognizes the amount with which the carrying amount exceeds the fair value as an impairment loss. And all assets with impairment losses of values among the assets to be disposed are requested to be recorded at the lesser of carrying amounts or net realizable values. Under the Japanese Accounting Principles, the impairment accounting will be applied to fixed assets as from a business year commencing on or after April 1, 2005. They also include the provision for earlier application.

5.5.1.10.2 *Accounting for Paid Vacation*

The Japanese Accounting Standards do not refer to the accounting of paid vacation, and related liabilities are not recognized under the accounting principles in Japan.

Under the U.S. Accounting Standards, if certain conditions are satisfied, liabilities are required to be recognized for the rights of employees for benefits of future paid vacations.

5.5.1.9.5 *Capitalization of Interest Charge*

Under the Japanese Accounting Standards, except certain special categories of business, interest charges are not capitalized but recorded as gains or losses for the period of accrual. Under the U.S. Accounting Standards, interest charges accrued during constructions of qualified assets are required to be capitalized as parts of acquisition costs.

5.5.1.9.7 *Accounting of Stock-Based Compensation*

In the Japanese Accounting Standards, there is no comprehensive accounting standard with regard to stock-based compensation. In general, when a stock option is granted, it is recorded at its issuance price, and when it is granted free of charge, liabilities and expenses are not recognized.

Under the U.S. Accounting Standards, the following two options are allowed for accounting of stock-based compensation.

Intrinsic Value Method: Compensation measured as a part with which a market trading price as of the date when a right is granted or another measurement date exceeds an exercise price is recognized over the period of providing services.

Fair Value Method: Compensation measured on the basis of a reward value as of the date when a right is granted is recognized over the period of providing services.

5.6 **Notes to Profit and Loss Statement**

	Year ended December 31, 2004	Year ended December 31, 2003
Total Research & Development Expense	$ 11,210,285	$ 4,723,158
Earnings per share information:		
Basis for computation of diluted loss per share for the year ended December 31, 2004 (pro forma):		
Shares of Common Stock outstanding	500,000	
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock (unaudited)	42,443,281	
Pro forma shares used to compute basic and diluted net loss per share (unaudited)	42,943,281	
Basis for computation of weighted average shares for forecasted loss per share for fiscal year ending December 31, 2005:		
Shares of Common Stock outstanding at December 31, 2004	500,000	
Shares of Preferred Stock converted into Common Stock upon initial public offering	66,782,856	
New Common Stock issued in initial public offering	27,123,288	
New Common Stock issued for over-allotment	1,284,257	
Total number of Shares used for earnings per share	95,690,401	

	Acquisition Cost		Fair Value		Unrealized Gain & Loss	
	2004	2003	2004	2003	2004	2003
Securities:						
Municipal Auction Rate Securities	$ 10,750,000	$ 1,250,000	$ 10,750,000	$ 1,250,000	—	—

	2004	2003
Property and equipment consist of the following:		
Leasehold improvements	$ 35,414	$ —
Furniture and equipment	321,136	39,852
Software	11,299	7,038
	367,849	46,890
Less accumulated depreciation and amortization	(59,662)	(14,640)
	$ 308,187	$ 32,250

Related-Party Transactions	Our board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, Director and Chairman, as a consultant to us. Under the terms of his agreement, Dr. Iwaki provides us with services in connection with the Company’s financing and business development activities. Dr. Iwaki presently is paid $20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services. During the year ended December 31, 2004, Dr. Iwaki earned $360,000 pursuant to this arrangement.	Our board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, Director and Chairman, as a consultant to us. Under the terms of his agreement, Dr. Iwaki provides us with services in connection with the Company’s financing and business development activities. Dr. Iwaki presently is paid $20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services. During the year ended December 31, 2003, Dr. Iwaki earned $190,000 pursuant to this arrangement.

	2004	2003
Tax Effect Accounting		
Deferred tax assets:		
Net operating loss carryforwards	$ 8,647,000	$ 4,347,000
Capitalized licenses	1,821,000	501,000
Research tax credits	327,000	—
Other, net	14,000	28,000
Net deferred tax assets	10,809,000	4,876,000
Less valuation allowance	(10,809,000)	(4,876,000)
	$ —	$ —
Retirement Benefit	Not applicable.	Not applicable.
Premise of Going Concern	Not applicable.	Not applicable.
Stock-Based Compensation:		
Stock-Based Compensation for Warrant		
At issue of Series B Preferred Stock	$ 19,405,950	$ —
At issue of Series C Preferred Stock	14,663,966	—
	$ 34,069,916	$ —
Deferred employee Stock-Based compensation	$ 1,419,300	$ —
Amortization of employee stock-based compensation	(224,579)	—
Unamortized deferred employee stock-based compensation	$ 1,194,721	$ —

	2004	2003
Stock Options:		
Persons Granted	Employees and Non-Employees	
Number of Shares authorized to be issued	2,000,000	2,000,000
Number of options outstanding	1,550,000	390,000
Number of Exercised Shares	0	0
Exercise price	$ 1.00	$ 1.00
Weighted average remaining contractual life of options	8.9 years	8.1 years
Common Stock Reserved for Future Issuance:		
Convertible Preferred Stock (as-converted)	66,782,856	20,750,000
Common Stock Warrant	13,356,572	3,650,000
Common Stock Options outstanding	1,550,000	390,000
Common Stock Options Authorized for Future Grant	450,000	1,610,000
Warrant		
Persons Granted	Founder	Founder
Exercise price	$ 0.10	$ 0.10
Number of Shares	12,856,572	3,650,000
Exercisable Period	Expire on September 26, 2007	Expire on September 26, 2007
Paid Amount	$ 1,285,657 aggregate exercise price.	$365,000 aggregate exercise price.
Exercising Condition	None.	None.
Persons Granted	BioVen Advisory	
Exercise price	$ 1.00	
Number of Shares	500,000	
Exercisable Period	Expires May 24, 2009.	
Paid Amount	$ 500,000 aggregate exercise price.	
Exercising Condition	None.	

Each warrant contains provisions for the adjustment of its exercise price and the number of shares issuable upon its exercise upon the occurrence of any stock dividend or stock split. The warrants have net exercise provisions under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the common stock at the time of exercise of the warrants after deduction of the aggregate exercise price.

	Year End Dec. 31, 2004		Year End Dec. 31, 2003	
Convertible Preferred Stock	Series A	Series B	Series A	Series B
Number of Authorized Shares	1,000,000	291,150	1,000,000	500,000
Number of Issued Shares	1,000,000	291,150	1,000,000	107,500
Carrying Value	$ 10,000,000	$ 26,812,651	$ 10,000,000	$ 9,656,547
Aggregate Liquidation Preference	$ 10,000,000	$ 29,115,000	$ 10,000,000	$ 10,750,000

Redeemable Convertible Preferred Stock	On September 2, 2004, the Company sold 27,667,856 shares of Series C redeemable convertible preferred stock at a purchase price of $1.62 per share for total net proceeds of $43,404,320, net of $1,417,607 of estimated issuance costs. The Series C preferred stock was sold at a price per share below our initial public offering price. Accordingly, pursuant to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, the Company recorded a deemed dividend on the Series C preferred stock of $31,264,677, which is equal to the number of shares of Series C preferred stock sold multiplied by the difference between the estimated fair value of the underlying common stock and the Series C preferred stock conversion price per share. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share and was reported as a charge to accumulated deficit and a credit to additional paid-in capital, with no net impact on total stockholders' equity.
Redeemable convertible preferred stock	The redemption provisions of the Series C preferred stock stipulate that at any time beginning in August 2010, upon request of holders of at least a majority of the then outstanding Series C preferred stock, the Company is required to redeem the Series C preferred stock of each requesting holder. The redemption shall take place in three equal annual installments with the initial redemption no later than 60 days after redemption is requested. The redemption price is equal to $1.62 plus any declared and unpaid dividends at the date of the redemption request and is limited to funds legally available. The Company is accreting the difference between the carrying value and

	redemption value of the Series C preferred stock over the period up to the first redemption date of August 2010.

Important Subsequent Event

Changes in Capitalization

We completed our initial public offering on February 4, 2005. In addition to the issuance of 30,000,000 shares of our common stock, we had the following changes in capitalization:

- filed a restated certificate of incorporation to provide for authorized capital stock of 200,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock; and
- reserved 20,300,000 shares of common stock for the 2004 Stock Incentive Plan and our 2000 General Stock Incentive Plan was terminated. The 450,000 shares available for future grant under this plan were also cancelled.

On March 8, 2005, the underwriters also exercised their overallotment option and we issued an additional 1,573,000 shares of our common stock at $3.53 per share.

The following sets forth the changes to our balance sheet as if the initial public offering had been completed as of December 31, 2004.

The pro forma information gives effect to (1) the filing of a restated certificate of incorporation to provide for authorized capital stock of 200,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock, (2) the sale by us of 30,000,000 shares of common stock at an initial public offering price of $3.88 per share and the receipt of estimated net proceeds of $104,299,964, after deducting estimated underwriting discounts and commissions and estimated offering costs payable by us, (3) the sale by us of 1,573,000 shares of common stock at an initial public offering price of $3.53 per share and the receipt of estimated net proceeds of $5,557,773, after deducting estimated underwriters discounts and commissions and estimated offering costs payable by us, and (4) the conversion of all of our outstanding shares of preferred stock into 66,782,856 shares of common stock upon the closing of our initial public offering.

	December 31, 2004	
	Actual	**Pro Forma**
Cash, cash equivalents and marketable securities available-for-sale	$ 50,801,328	$ 160,660,065
Redeemable convertible preferred stock, $0.01 par value; actual—27,667,856 shares authorized, issued and outstanding; pro forma—no shares authorized, issued and outstanding	$ 43,483,076	$ —
Stockholders' equity:		
Convertible preferred stock, $0.01 par value; actual—1,291,150 shares authorized, issued and outstanding; pro forma—5,000,000 shares authorized; no shares issued and outstanding	12,912	—
Common stock, $0.001 par value; actual—83,000,000 shares authorized; 500,000 shares issued and outstanding; pro forma—200,000,000 shares authorized; 98,855,856 shares issued and outstanding	500	98,856
Additional paid-in capital	103,603,132	256,858,501
Deferred employee stock-based compensation	(1,194,721)	(1,194,721)
Deficit accumulated during the development stage	(94,752,701)	(94,752,701)
Total stockholders' equity	$ 7,669,122	$ 161,009,935

6. Situations of Production, Order Receiving and Sale

The Company engages mainly in research and development and not in production and order receiving.

Revenues recorded with the Company's main trade partners during 2004 and the ratio against such sales are as follows:

Trade Partner	Year ended December 31, 2004	Ratio	Year ended December 31, 2003	Ratio
Asahi Kasei Pharma Corp.	455,195	92.8%	—	—

7. **Change of Directors**

Not applicable.