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): August 15, 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 August 15, 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 first half of 2005 (the "Japanese Filing"). A copy of the certified English translation of the Japanese Filing is attached hereto as Exhibit 99.1.

The Japanese Filing includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond the Company's control. The Company's actual results will differ from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption "Risk Factors" and these differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, forecasts, discussions regarding the Company's operating strategy, growth strategy, licensing and acquisition strategy, cost savings initiatives, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. In the Japanese Filing, for example, the Company makes forward-looking statements regarding forecasts and expectations about the rate of revenue growth and the reasons for that expected growth and the achievement of profitability. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would" or similar expressions. For those statements, the Company claims the protection of the safe harbor for forward-looking statements contained in the U.S. Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

The information contained in the Japanese Filing is not a complete description of the Company's business or the risks associated with an investment in the Company's common stock. The Company urges you to carefully review and consider the various disclosures made by the Company in the Japanese Filing and in the Company's other reports filed with the Securities and Exchange Commission.

Item 7.01. Regulation FD Disclosure.

The Company will hold a live Japanese language meeting at Tokyo Shoken Kaikan 9F, 1-5-8 Nihonbashi-Kayabacho, Chuo-ku, Tokyo, at 10:00 a.m. on Wednesday, August 17, 2005 (Japanese Standard Time) to discuss the Company's financial results for the six months ended June 30, 2005 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	Japanese Filing dated August 15, 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: August 15, 2005

MEDICINOVA, INC.

By: /s/ TAKASHI KIYOIZUMI

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

EXHIBIT INDEX

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Exhibit 99.1

Financial Statements For the Six Months Ended June 30, 2005

August 15, 2005

Name of Listed Company: MEDICINOVA, INC. Listed Exchanges: Hercules, Osaka Ex.
Code Number: 4875 Location of Head Office: California, U.S.A.
(URL http://www.medicinova.com)
Representative Officer: Takashi Kiyoizumi, President & CEO

Contact: Joji Suzuki, Vice President, Finance, TEL: (03) 3519-5010
Date of Meeting of Board of Directors for Approving Financial Statements: August 15, 2005
Interim Dividend System: N/A
Date of Interim Dividend Payment: N/A
System of trading unit of shares: Adopted (Unit: 1,000 shares)

The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report and the financial statements and notes thereto included in our Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission on August 15, 2005. Operating results are not necessarily indicative of results that may occur in future periods.

This report includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results will differ from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption "Risk Factors" and these differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, forecasts, discussions regarding our operating strategy, growth strategy, acquisition strategy, cost savings initiatives, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. In this report, for example, we make forward-looking statements regarding forecasts and our expectations about the rate of revenue growth and the reasons for that expected growth and our achievement of profitability. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words "believe," "expect," "anticipate," "intend," "estimate," "project," "can," "could," "may," "will," "would" or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the U.S. Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

1. The financial statements for the six months ended June 30, 2005 and 2004 and for the year ended December 31, 2004 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	%
For the six months ended June 30, 2005	$ 33,887	(81.9)	$ (13,837,640)	—	$ (12,042,242)	—
For the six months ended June 30, 2004	186,960	—	(26,740,456)	—	(26,696,604)	—
Year ended December 31, 2004	490,282	—	(48,612,386)	—	(48,272,603)	—

	Net loss	Basic net loss per share	Diluted net loss per share
For the six months ended June 30, 2005	$(12,042,242)	$ (0.15)	—
For the six months ended June 30, 2004	(26,696,604)	(53.39)	—
Year ended December 31, 2004	(48,272,603)	(159.23)	—

(Notes)
(a) Profit (loss) from investment by equity method during:
The six months ended June 30, 2005: N/A
The six months ended June 30, 2004: N/A
The year ended December 31, 2004: N/A
(b) Weighted average number of outstanding shares of common stock during:
The six months ended June 30, 2005: 79,558,668 shares
The six months ended June 30, 2004: 500,000 shares
The year ended December 31, 2004: 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 same period in previous year.

(2) Financial Position

	Total assets	Stockholders' equity	Equity ratio (ratio of equity to total assets)	Stockholders' equity per share
As of June 30, 2005	$154,577,597	$ 149,319,855	96.6%	$ 1.51
As of June 30, 2004	15,631,681	14,459,322	92.5	28.92
As of December 31, 2004	53,768,595	7,669,122	14.3	15.34

(Notes)
(a) Shares of common stock outstanding as of:
June 30, 2005: 98,855,856 shares
June 30, 2004: 500,000 shares
December 31, 2004: 500,000 shares
(b) Treasury shares as of:
June 30, 2005: 0 shares
June 30, 2004: 0 shares
December 31, 2004: 0 shares

(3) 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 period-end
For the six months ended June 30, 2005	$ (9,833,590)	$ (112,172,082)	$ 111,126,752	$ 27,922,408
For the six months ended June 30, 2004	(7,005,554)	(149,985)	16,856,104	13,941,264
Year ended December 31, 2004	(13,546,476)	(11,071,235)	59,178,340	38,801,328

2. Financial Results Forecast for the Year Ending December 31, 2005

	Revenues	Operating loss	Net loss	Dividend per share
For the year ending December 31, 2005	$ 750,000	$(37,100,000)	$(33,400,000)	$0.00

(Reference) Expected loss per share (for full year): $0.34
(Notes) Using 98,855,856 shares 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 our 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 our control, which may cause our actual results to differ materially from the above estimates. These risks include the risk factors detailed in our Securities and Exchange Commission filings, including our Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission on August 15, 2005. 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**

We aim to become 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 licenses to product candidates, we follow a basic policy that:

Ÿ a product candidate should be in the late pre-clinical or early clinical development stage and should have extensive safety and efficacy data, and

Ÿ 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 distribute profit in the foreseeable future, we will pursue maximization of stockholders' value when and if we eventually distribute profit. However, we are still at the early stage of business development. It is our policy for the time being to retain earnings for the growth and development of the operations.

2.3. **Reducing the Investing Unit**

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

2.4. **Target Management Indices**

It is expected that we 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 our business management targets 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**

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

Ÿ *Dual pathway development approaches*

We have acquired rights in various product candidates that are based on proven pharmacology, but have features distinct from existing treatments. In developing these product candidates, we use 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, thereby increasing 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.

Ÿ *Continuous expansion of pipelines for promising product candidates*

We continue to identify and acquire licenses for product candidates in the late pre-clinical or early clinical development stage. We utilizes our 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. We are in active negotiations to acquire licenses for additional product candidates, making the best use of this advantage. In pursuing licenses for product candidates, we conduct 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 can be mitigated by expanding and further diversifying our pipelines of product candidates.

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

We intend to actively pursue strategic collaborations with major biotechnological or pharmaceutical companies to draw on their expertise on development, pharmaceutical regulation and commercialization. We have made contact with several companies that have shown interest in our partnership program. In the area of 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.

Ÿ *Continuous strengthening of the management team*

While developing the existing product candidate portfolio, we 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 efficient implementation of our development programs.

2.6. Issues To Be Addressed—Risk Factors

In pursuing the strategies described in Section 2.5, the following risks may adversely affect our business.

2.6.1. Risks Related to Our Business

2.6.1.1. *We expect our net losses to continue for at least several years and we are unable to predict the extent of our future losses.*

We are a development stage specialty pharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. 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. For the six months ended June 30, 2005, we had a net loss of $12.0 million. We expect our 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 stock-based compensation, will continue to reduce our stockholders' equity and working capital.

We expect our development expenses to increase in connection with our planned clinical trials for our product candidates and any other development projects that we may initiate. In addition, we expect to incur increased general and administrative expenses as well as the increased costs to operate as a public company. Consequently, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

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

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 generated any product revenue and have funded our operations primarily from sales of our securities. Our only source of revenues since inception has been 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. Our contract with Asahi Kasei Pharma has been completed and we do not expect to generate further revenue from that agreement. We anticipate that we will continue to receive modest revenues for rendering consulting services and that, prior to our commercialization of a product candidate, our consulting revenues, together with out-licensing upfront and milestone payments, will be our primary source of revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with market potential. We may never succeed in these activities, and may not generate sufficient revenues to continue our business operations or achieve profitability.

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

We license the rights to develop and market our product candidates. Currently, we have licensed six compounds for the development of seven product candidates. They are:

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

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

If any of our license agreements is terminated, then we would have no further rights to develop and commercialize the product candidate which is the subject of the license. The termination of any of our license agreements would significantly and adversely affect our business.

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

Six of our seven product candidates are in clinical development, the process that is required to receive regulatory approval for commercial sale. The regulatory approval process is long, complex and costly. It may take several years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage which may result in our inability to market and sell products derived from our product candidates and to generate product revenues. Of the large number of drugs in development, only a small percentage result in the submission of a new drug application to the Food and Drug Administration, or 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 suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

In connection with clinical trials, we face risks that:

- 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;
- the results may not confirm the positive results of earlier trials; and
- the results may not be acceptable to the FDA or other regulatory agencies.

To date, the FDA has accepted Investigational New Drug, or IND, applications for five of our seven product candidates. We have filed Clinical Trial Authorization, or CTA, applications, the equivalent of a U.S. IND, in nine European countries to conduct a Phase II study for MN-166 in patients with multiple sclerosis. Four of these applications are approved and the remaining five are under active review. We cannot conduct human clinical trials in the United States or in Eastern Europe on our remaining product candidate until an IND or CTA application is in effect and there can be no assurance that the regulatory authorities, including the FDA, will allow our applications to go into effect.

The commencement of clinical trials can be delayed for a variety of 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 contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of 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:

- Ÿ ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- Ÿ our failure or inability to conduct clinical trials in compliance with regulatory requirements;
- Ÿ lower than anticipated retention rates of patients in clinical trials;
- Ÿ serious adverse events or side effects experienced by participants; or
- Ÿ insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors described above may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays in our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed.

2.6.1.5. *If we fail to identify and license or acquire other product candidates, we will not be able to expand our business.*

Since we have limited internal discovery capabilities, our business is substantially dependent on our ability to license or acquire late preclinical-stage or early clinical-stage product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive and many of our competitors have greater resources than us. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

Moreover, product candidate acquisitions that we do complete involve numerous risks, including:

- Ÿ difficulties in integrating the development program for the acquired product candidates into our existing operations;
- Ÿ diversion of financial and management resources from existing operations;
- Ÿ risks of entering new markets or new technologies;
- Ÿ inability to generate sufficient revenues to offset acquisition costs; and
- Ÿ delays that may result from us having to perform unanticipated pre-clinical trials or other tests on the product candidate.

If we are not successful in identifying and licensing or acquiring other product candidates, we will not be able to grow our revenues with sales from new products.

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

We have consumed substantial amounts of capital since our inception. From our inception to June 30, 2005, we used $38.5 million in cash to fund our operating activities and acquisitions of property and equipment. Although we believe our existing cash and investments will be sufficient to fund our anticipated cash requirements through 2006, we will require significant additional financing in the

future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- Ÿ progress in, and the costs of, our clinical trials;
- Ÿ the costs of securing manufacturing arrangements for clinical or commercial production;
- Ÿ the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- Ÿ the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approval to market our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings or by licensing all or a portion of our product candidates. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue other business opportunities that require financial commitments and we may be required to:

- Ÿ terminate or delay clinical trials for one or more of our product candidates;
- Ÿ delay establishing sales and marketing capabilities;
- Ÿ curtail efforts to acquire new product candidates; or
- Ÿ relinquish rights to our technologies or product candidates.

2.6.1.7. *We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates.*

A key aspect of our strategy is to enter into collaborations with third-party partners whereby we license selected product candidates to larger pharmaceutical companies that are 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 third-party partners and currently do not expect to do so until we have successfully completed further studies for one of our partnering program product candidates.

By entering into these strategic collaborations, we may rely on our partners for financial resources and for development, commercialization and regulatory expertise. Our partners may fail to develop or effectively commercialize products using our product candidates because they:

- Ÿ do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- Ÿ decide to pursue a competitive potential product that has been developed outside of the collaboration; or
- Ÿ cannot obtain the necessary regulatory approvals.

We may not be able to enter into collaborations on acceptable terms, if at all. We also face competition in our search for partners with whom we may collaborate.

2.6.1.8. *We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that may hamper our ability to successfully develop and commercialize our product candidates.*

Although we design and manage our current clinical trials, we do not have the ability to conduct clinical trials directly for our product candidates. We will rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis. In the course of clinical development, we have contracted and will continue to contract with a number of these 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; Paragon, Inc. of Irvine, California and Quintiles, Inc. of Morrisville, North Carolina.

Our clinical trials may be delayed, suspended or terminated if:

- Ÿ the third parties upon whom we rely do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;
- Ÿ such third parties needs to be replaced; or
- Ÿ the quality or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by the third parties upon whom we rely may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of our 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. *Our product candidates may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.*

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

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

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product likely will not achieve market acceptance.

2.6.1.10. *We are dependent on our management team, particularly Takashi Kiyoizumi, M.D., Ph.D., a founder and our chief executive officer, and Yuichi Iwaki, M.D., Ph.D., a founder and executive chairman of our board of directors, and 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.*

We are dependent upon the continued services of our executive officers and other key personnel, particularly Takashi Kiyoizumi, M.D., Ph.D., one of our founders and our chief executive officer, and Yuichi Iwaki, M.D., Ph.D, one of our founders and the executive chairman of our board of directors, who have been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that all of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates as part of our partnering program make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing project management personnel because of the highly technical nature of our product development programs.

As we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our drug development programs depend on our ability to attract and retain highly experienced development and regulatory personnel. In addition, we will need to hire additional personnel as we continue to expand our clinical development and other development activities. If we are successful in developing candidates for commercialization, we will need to hire additional personnel to direct those activities as well. We face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our offices are located. Our short operating history and the uncertainties attendant to being a development-stage specialty pharmaceutical company with limited capital resources could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives.

Although we have employment agreements with key members of management, 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 replacements and our business would be harmed as a result.

2.6.1.11. *If we are unable to establish our sales and distribution capabilities, we will be unable to successfully commercialize our core product candidates.*

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in developing and obtaining regulatory approvals for the product candidates in our strategic core programs or acquire other products, we will need to establish sales, marketing and distribution capabilities. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products. Although we intend to establish strategic collaborations to market the products in our strategic core programs outside the United States, if we are unable to establish such collaborations, we may be required to market our strategic core product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

2.6.1.12. *We will need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.*

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

To manage our growth, we will be required to continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. Meeting our public reporting obligations and other regulatory requirements in the United States and Japan now that we are a public company will place additional demands on our limited resources. We may not successfully manage the expansion of our operations and, accordingly, may not achieve our development and commercialization goals.

2.6.1.13. *Relying on third-party manufacturers may result in delays in our clinical trials and product introductions as well as increased costs.*

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future. We are contracting with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty. To date, these manufacturers have met the requirements of our programs.

Our manufacturers will be obliged to operate in accordance with FDA-mandated or International Convention on Harmonization (ICH) current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of our products into the market. In addition, changing contract manufacturers is difficult. For example, doing so requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

2.6.1.14. *We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.*

To date, our product candidates have been manufactured in small quantities for pre-clinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a

product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates will require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could result in a material adverse effect on our business, financial condition and results of operations.

2.6.1.15. *Materials necessary to manufacture our products may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our products.*

We rely on the manufacturers for our products to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials and for commercial distribution, if we obtain marketing approval for any of our products. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of our products would be delayed, significantly impacting our ability to develop the product candidate. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our products, the commercial launch of our products would be delayed or there would be a shortage in supply of our products, which would materially affect our ability to generate revenues from the sale of our products.

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 foreign 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, as well as one U.S. patent application regarding MN-029.

The patent protection of our product candidates and technology involves complex legal and factual questions. In general, our license agreements give us a right, but not an 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:

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

The degree of future protection for our proprietary rights 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 U.S. or foreign laws;
- 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 which provide 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, and are not aware of any threatened 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 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. If we become involved in litigation, it 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 collaborators 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;

- Ÿ we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms; and
- Ÿ significant cost and expenses, as well as distraction of our management from our business.

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 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. None of our product candidates has been approved, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial 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 post-approval studies, including additional research and development and clinical trials, may be required. 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 partners, 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 partners, 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 abroad.

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

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution.

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, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs.

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, biologies 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 partners' 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 others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We currently have 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 partners develop. Product liability claims could have a material adverse effect on our business and results of operations. 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 foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, 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 were sold at lower prices. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential 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 partnerships or licenses.

3. Operating Results and Financial Condition

3.1 Operating Results

Operating results	For the six months ended June 30, 2005	For the six months ended June 30, 2004	Change from previous period	%
Revenues	$33,887	$186,960	$(153,073)	(81.9)
Operating Loss	(13,837,640)	(26,740,456)	12,902,816	—
Net Loss	(12,042,242)	(26,696,604)	14,654,362	—

3.1.1 *Overview*

Despite a sharp rise in oil prices, a burgeoning fiscal deficit, increasing interest rates and other destabilizing factors, the U.S. 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 U.S. 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 achieved further progress in our development programs during the first six months of the fiscal year 2005. We initiated the enrollment of patients in an additional phase I study for MN-221 (premature labor) in the U.S. during the first quarter of the fiscal year 2005. During the same period, we also initiated the enrollment of patients in a phase II study for MN-001 (asthma and interstitial cystitis). During the second quarter of the fiscal year 2005, we initiated the enrollment of patients in a second phase I study for MN-029 (solid tumor). Our phase II study for MN-305 (General Anxiety Disorder) and the preparation for a phase I study for MN-246 (urinary incontinence), are in progress and in line with our expectations.

Revenues

Our revenues during the first six months of the fiscal year 2005 have been generated from development management services performed under a master services agreement. Our revenue decreased to $34,000 for the six months ended June 30, 2005 from $187,000 for the six months ended June 30, 2004. The decrease primarily was due to the completion of the Asahi Kasei master service agreement and the fluctuation of the activity under the Argenes master service agreement.

Research and Development

Research and development expenses increased to $10.7 million for the six months ended June 30, 2005 from $6.1 million for the six months ended June 30, 2004. This increase primarily was due to:

- an increase of $1.2 million in our strategic core programs as a result of $2.3 million of clinical trial and related costs, partially offset by a $1.1 million decrease in other costs, primarily consisting of licensing and milestone payments;
- an increase of $2.8 million in our partnering programs as a result of a $4.2 million increase in clinical trial and related costs, partially offset by a $1.4 million decrease in other costs, primarily consisting of licensing and translation fees; and
- an increase of $0.6 million in unallocated expenses as a result of increased salaries and related personnel costs due to expansion of our development staff.

We expect that fees paid to external service providers will continue to increase as we may acquire new product candidates and continue development of our existing product candidates. We anticipate that our research and development expenses will continue to increase in future periods as we expend additional capital to conduct clinical trials and develop our product candidates.

General and Administrative

General and administrative expenses increased to $3.0 million for the six months ended June 30, 2005 from $1.2 million for the six months ended June 30, 2004. This increase primarily was due to $0.6 million of salaries and related costs as we expanded our general and administrative functions to support our operations, $0.4 million of legal and accounting fees, $0.2 million of insurance premiums and $0.6 million of other expenses. We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance and professional fees associated with operating as a public company and to support the future growth of our research and development organization.

Stock-Based Compensation

Stock-based compensation expenses decreased to $0.2 million for the six months ended June 30, 2005 from $19.4 million for the six months ended June 30, 2004. The decrease primarily was 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 in 2004. During the six months ended June 30, 2004, pursuant to the anti-dilution provisions of the warrants originally issued in September 2000 to our founders and as a result of the sale of our Series B preferred stock, we adjusted the warrants to provide that our two founders may purchase an aggregate of 7,323,000 shares of our common stock. As a result, we recorded $19.4 million of stock-based compensation expense to reflect the difference between the deemed fair value of the underlying common stock and the warrant exercise price at June 30, 2004 for all warrants issued to date. We had no issuances of options or warrants during the comparable period in 2005 that required us to record stock-based compensation expenses.

Other Income, Net

Other income, net is primarily interest income earned on our cash and investment balances and totaled $1,795,000 and $44,000 for the six months ended June 30, 2005 and 2004, respectively. The increase in income amounts from 2004 to 2005 primarily was due to the increase in our average cash and investment balances as a result of the proceeds from our initial public offering.

Operating Loss and Net Loss

Operating loss was $13.8 million and net loss was $12.0 million for the six months ended June 30, 2005. Both operating loss and net loss decreased by $12.9 million and $14.7 million, respectively, over the prior term for the reasons noted above.

3. 2 Financial Conditions

3.2.1 Assets, Liabilities and Stockholders' Equity

Total assets increased to $154.6 million at June 30, 2005 from $53.8 million at December 31, 2004. Cash and cash equivalents and marketable securities available-for-sale increased by $101.1 million due to those factors noted in Section 3.2.2. Other assets decreased by $2.2 million as a result of the completion of our initial public offering. Accrued expenses increased to $3.8 million at June 30, 2005 from $1.6 million at December 31, 2004 primarily due to costs accrued related to the research and development activities. Redeemable convertible preferred stock decreased by $43.5 million as a result of automatic conversion of preferred stock outstanding into common stock in connection with our initial public offering. Stockholders' equity increased to $149.3 million at June 30, 2005 from $7.7 million at December 31, 2004 as a result of the sale of 30,000,000 shares of common stock in connection with our initial public offering, the sale of 1,573,000 shares of common stock pursuant to the partial exercise, by our underwriters, of an over-allotment option, and the automatic conversion of preferred stock.

3.2.2 *Cash Flows*

	For the six months ended June 30, 2005	For the six months ended June 30, 2004	Change from previous period
Net cash used in operating activities	$(9,833,590)	$(7,005,554)	$(2,828,036)
Net cash used in investing activities	(112,172,082)	(149,985)	(112,022,097)
Net cash provided by financing activities	111,126,752	16,856,104	94,270,648
Cash and cash equivalents, beginning of period	38,801,328	4,240,699	34,560,629
Cash and cash equivalents, end of period	27,922,408	13,941,264	13,981,144

As of June 30, 2005, we had $27.9 million in cash and cash equivalents as compared to $38.8 million as of December 31, 2004, a decrease of $10.9 million. Net cash used in operating activities amounted to $9.8 million for the six months ended June 30, 2005, primarily reflecting the net loss occurring for this period of $12.0 million. Net cash used in investing activities for the six months ended June 30, 2005 consisted of $111.9 million for the net purchases of investments and $0.3 million of capital equipment purchases. Net cash provided by financing activities amounted to $111.1 million for the six months ended June 30, 2005, primarily reflecting the sale of common stock upon the completion of our initial public offering and the related over-allotment option exercised by our underwriters.

	Year ended December 31, 2001	Year ended December 31, 2002	Year ended December 31, 2003	Year ended December 31, 2004	Six months ended June 30, 2005
Stockholders' Equity Ratio	96.1%	70.8%	81.2%	14.3%	96.6%
Stockholders' Equity Ratio on Market Value Basis (%)	—	—	—	—	131.9%
Debt Repayment Term (Years)	—	—	—	—	—
Interest Coverage Ratio (Times)	—	—	—	—	—

Stockholders' equity ratio (%): Total stockholders' equity / Total assets
Stockholders' equity ratio on market value basis (%): Market capitalization/Total assets
Debt Repayment Term (Years): N/A
Interest coverage ratio (Times): N/A

(Note)
Total amount of market value of shares is calculated by using the closing price of shares at the end of term times the number of shares outstanding at the end of term.

4. Forecast of Performance Results for Next Term (Fiscal Year ended December 31, 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	(37,100,000)	11,512,386	—
Net Loss	(33,400,000)	14,872,603	—

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 during the second half of the fiscal year 2005. We also expect operating loss in 2005 will decrease by $11.5 million from $48.6 million in 2004. We anticipate a continued increase in both research and development and general and administrative expenditures in 2005 over 2004 due to the progress of our portfolio of product candidates and the expanding administrative organization supporting this growth. 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 $14.9 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 Semi-Annual Financial Statements

*5.1 Semi-Annual Balance Sheet**

	(A) As of June 30, 2005	%	As of June 30, 2004	%	(B) As of December 31, 2004	%	(A) – (B) Increase (decrease)
	(Unaudited)		(Unaudited)				
Assets							
Current Assets							
Cash and cash equivalents	$27,922,408		$13,941,264		$38,801,328		$(10,878,920)
Marketable securities available-for-sale	123,972,396		1,250,000		12,000,000		111,972,396
Prepaid expenses and other current assets	2,163,334		272,293		487,576		1,675,758
Total Current Assets	154,058,138	99.7	15,463,557	98.9	51,288,904	95.4	102,769,234
Property and equipment, net	519,459	0.3	168,124	1.1	308,187	0.6	211,272
Other assets	—	0.0	—	0.0	2,171,504	4.0	(2,171,504)
Total Assets	$154,577,597	100.0	$15,631,681	100.0	$53,768,595	100.0	$100,809,002
Liabilities and stockholders' equity							
Current Liabilities:							
Accounts payable	$1,090,255		$699,629		$469,798		$620,457
Accrued expenses	3,769,378		307,829		1,552,622		2,216,756
Accrued payroll and related expenses	338,671		164,901		562,656		(223,985)
Total Current Liabilities	5,198,304	3.4	1,172,359	7.5	2,585,076	4.8	2,613,228
Deferred Rent	59,438	0.0	—	0.0	31,321	0.1	28,117
Total liabilities	5,257,742	3.4	1,172,359	7.5	2,616,397	4.9	2,641,345
Redeemable Convertible Preferred Stock**	—	0.0	—	0.0	43,483,076	80.9	(43,483,076)
Number of authorized shares:							
No shares as of June 30, 2005 and 2004							
27,667,856 shares as of December 31, 2004							
Number of issued shares:							
No shares as of June 30, 2005 and 2004							
27,667,856 shares as of December 31, 2004							
Stockholders' Equity							
Convertible Preferred Stock, $0.01 par value	—	0.0	12,912	0.1	12,912	0.0	(12,912)
Number of authorized shares:							
5,000,000 shares as of June 30, 2005 and 2004							
1,291,150 shares as of December 31, 2004							
Number of issued shares:							
No shares as of June 30, 2005							
1,291,150 shares as of June 30, 2004							
1,291,150 shares as of December 31, 2004							
Common Stock, $0.001 par value	98,856	0.1	500	0.0	500	0.0	98,356
Number of authorized shares:							
200,000,000 shares as of June 30, 2005							
80,000,000 shares as of June 30, 2004							
83,000,000 shares as of December 31, 2004							
Number of issued shares:							
98,855,856 shares as of June 30, 2005							
500,000 shares as of June 30, 2004							
500,000 shares as of December 31, 2004							
Additional paid-in capital	257,041,721	166.2	57,406,689	367.2	103,603,132	192.7	153,438,589
Deferred Employee Stock-Based Compensation	(961,205)	(0.6)	(1,127,510)	(7.2)	(1,194,721)	(2.2)	233,516
Accumulated other comprehensive loss	(44,885)	(0.0)	—	0.0	—	0.0	(44,885)
Deficit accumulated during the development stage	(106,814,632)	(69.1)	(41,833,269)	(267.6)	(94,752,701)	(176.2)	(12,061,931)
Total Stockholders' Equity	149,319,855	96.6	14,459,322	92.5	7,669,122	14.3	141,650,733
Total Liabilities and Stockholders' Equity	$154,577,597	100.0	$15,631,681	100.0	$53,768,595	100.0	$100,809,002

* Please see Notes to Financial Statements below.
** Included in long-term liability section of Japanese language version of this Tanshin.

*5.2 Semi-Annual Statement of Operations**

	(A) Six months ended June 30, 2005	%	(B) Six months ended June 30, 2004	%	(A) – (B) Increase (decrease)	Year ended December 31, 2004	%
	(Unaudited)		(Unaudited)				
Revenues	$33,887	100.0	$186,960	100.0	$(153,073)	$490,282	100.0
Operating Expenses							
Cost of revenues	26,059		165,760		(139,701)	437,582	
Research and development	10,671,016		6,108,352		4,562,664	11,210,285	
General and administrative	2,964,336		1,223,364		1,740,972	3,160,306	
Amortization of employee stock-based compensation and founders' warrants:							
Research and development	141,140		13,782		127,358	106,770	
General and administrative	68,976		19,416,158		(19,347,182)	34,187,725	
Total Operating Expenses	13,871,527	40934.7	26,927,416	14402.8	(13,055,889)	49,102,668	10015.2
Operating Loss	(13,837,640)	(40834.7)	(26,740,456)	(14302.8)	12,902,816	(48,612,386)	(9915.2)
Other Income, net	1,795,398	5,298.2	43,852	23.5	1,751,546	339,783	69.3
Net Loss	(12,042,242)	(35536.5)	(26,696,604)	(14279.3)	14,654,362	(48,272,603)	(9845.9)
Accretion to redemption value of redeemable convertible preferred stock	(19,689)		—		(19,689)	(78,756)	
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	—		—		—	(31,264,677)	
Net loss applicable to common stockholders	$(12,061,931)		$(26,696,604)		$14,634,673	$(79,616,036)	
Basic and diluted net loss per share	(0.15)		(53.39)			(159.23)	
Shares used to compute basic and diluted net loss per share	79,558,668		500,000			500,000	

* Please see Notes to Financial Statements below.

5.3 Semi-Annual Cash Flow Statement

	(A) Six months ended June 30, 2005	(B) Six months ended June 30, 2004	(A) – (B) Increase (decrease)	Year ended December 31, 2004
	(Unaudited)	(Unaudited)		
Operating activities:				
Net loss	$(12,042,242)	$(26,696,604)	$14,654,362	$(48,272,603)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash stock-based compensation	210,116	19,429,940	(19,219,824)	34,294,495
Depreciation and amortization	54,961	14,111	40,850	45,298
Amortization of premium/discount on marketable securities	(111,432)	—	(111,432)	—
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(1,675,758)	(163,933)	(1,508,519)	(379,216)
Accounts payable, accrued expenses and deferred rent	3,954,750	383,630	3,571,120	340,493
Accrued compensation and related expenses	(223,985)	27,302	(251,287)	425,057
Cash flows used in operating activities	(9,833,590)	(7,005,554)	(2,824,730)	(13,546,476)
Investing activities:				
Purchases of marketable securities available-for-sale	(186,305,849)	—	(186,309,155)	(10,750,000)
Maturities of marketable securities available-for-sale	74,400,000	—	74,400,000	—
Acquisitions of property and equipment	(266,233)	(149,985)	(116,248)	(321,235)
Net cash used in investing activities	(112,172,082)	(149,985)	(112,025,403)	(11,071,235)
Financing activities:				
Net proceeds from the sale of common stock	111,126,752	—	111,126,752	(1,082,084)
Sales of preferred stock, net of issuance costs	—	17,156,104	(17,156,104)	60,560,424
Advances received for the sale of convertible preferred stock	—	(300,000)	300,000	(300,000)
Net cash provided by financing activities	111,126,752	16,856,104	94,270,648	59,178,340
Net increase in cash and cash equivalents	(10,878,920)	9,700,565	(20,579,485)	34,560,629
Cash and cash equivalents, beginning of period	38,801,328	4,240,699	34,560,629	4,240,699
Cash and cash equivalents, end of period	$27,922,408	$13,941,264	$13,981,144	$38,801,328

5.4 Important Basic Matters for Compiling Semi-Annual Financial Statements

5.4.1 Main Accounting Policy

5.4.1.1 *Marketable Securities Available-for-Sale*

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.

5.4.1.2 *Property and Equipment*

Our 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. Our current lease will expire in 2008.

5.4.1.3 *Initial Public Offering Costs*

Costs associated with our initial public offering in February 2005 were 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 were capitalized as other assets.

5.4.1.4 *Translation of Foreign Currency Transactions*

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.

5.4.1.5 *Operating Leases*

We lease our facilities under operating leases. The minimum annual rent on our 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.

5.4.1.6 *Recording Standard of Revenue and Expenses*

5.4.1.6.1 *Revenue Recognition*

In connection with the management of clinical trials, we pay, on behalf of our 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, we charge management fees based on negotiated hourly rates pursuant to master services agreements with Asahi Kasei Pharma Corporation and Argenes Inc. We recognize 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.

5.4.1.6.2 *Stock-Based Compensation*

We have elected to follow Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for our employee stock options and warrants as permitted by Statement of Financial Accounting Standards, or SFAS, No. 123, Accounting for Stock-Based Compensation. Under APB Opinion No. 25, if the exercise price of our 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 our technology, (ii) our financial position and (iii) the fair value of our common stock or preferred stock as determined in arm's-length transactions.

5.4.1.6.3 *Comprehensive Income*

We have 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.

5.4.1.7 *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.

5.4.1.8 *Impairment of Fixed Assets*

We review 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.

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

We have 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:

5.4.1.9.1 *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, we must study whether the impairment of values occurs or not. If any indication of impairment is recognized, we have 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 so, we recognize 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.

5.4.1.9.2 *Accounting of Stock-Based Compensation*

Under U.S. accounting standards, stock-based compensation such as employee stock options and warrants is accounted for in accordance with Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123 allows entities to continue to apply the intrinsic-value-based method prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and provide pro forma disclosures for employee stock-based compensation as if the fair-value-based method of SFAS No. 123 had been applied.

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123R, *Share-Based Payment*, which requires stock-based compensation for an award of equity instruments, including stock options and employee stock purchase rights, issued to employees to be recognized as a cost in the financial statements. The cost of these awards is measured according to the grant date fair value of the stock options and is recognized over the period during which an employee is required to provide service in exchange for the award, which is usually the vesting period. The requirements of SFAS No. 123R are effective for us in the first interim or annual period beginning after June 15, 2005.

In Japan, the exposure draft for stock-based compensation accounting was released in December 2004. The standard is expected to be effective in the first interim or annual period beginning after April 1, 2006. Currently, there is no comprehensive accounting standard with regard to stock-based compensation under Japanese Accounting Standards. 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.

5.4.1.9.3 *Comprehensive Income*

Under U.S. accounting standards, all components of comprehensive income, including net income, must be reported in the financial statements for 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. Under Japanese accounting standards, there is no requirement to disclose components of comprehensive income.

5.5 Notes to Semi-Annual Financial Statements

5.5.1 Notes to Semi-Annual Balance Sheet

5.5.1.1 *Accumulated Depreciation*

	June 30, 2005	June 30, 2004	December 31, 2004
Accumulated depreciation	$114,624	$ 28,475	$ 59,662

5.5.1.2 *Redeemable Convertible Preferred Stock*

June 30, 2005	June 30, 2004	December 31, 2004
None	None	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. We are 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.

5.5.2 Notes to Semi-Annual Statement of Operations

5.5.2.1 *Depreciation and amortization Expense*

	Six months ended June 30, 2005	Six months ended June 30, 2004	Year ended December 31, 2004
Depreciation and amortization expense	$ 54,961	$ 14,111	$ 45,298

5.5.3 Notes to Semi-Annual Statement of Cash Flows

None.

5.5.4 Facility Lease

In March 2005, we amended our non-cancellable operating lease for our corporate headquarters to expand our leased space from 11,375 square feet to 16,609 square feet.

Future minimum payments are as follows at June 30, 2005:

	Operating Lease
Six months ending December 31, 2005	$ 308,927
2006	636,125
2007	656,056
2008	54,810
	$ 1,655,918

Future minimum payments were as follows at June 30, 2004:

	Operating Lease
Six months ending December 31, 2004	$ 150,856
2005	400,392
2006	435,356
2007	448,997
2008	37,511
	$ 1,473,112

Future minimum payments were as follows at December 31, 2004:

	Operating Lease
2005	$ 402,666
2006	435,356
2007	448,997
2008	37,511
	$ 1,324,530

5.5.5 Marketable Securities Available-for-Sale

Investment securities available-for-sale consists of certificates of deposit, high-grade auction rate securities (ARS), corporate debt securities and U.S. government debt securities. All of the corporate debt securities and U.S. government debt securities have contractual maturities of 12 months or less as of June 30, 2005. The ARS have either a stated or perpetual maturity that is structured with short-term holding periods. At the beginning of each holding period, an auction takes place which determines the coupon rate or dividend. At the end of each holding period, a new auction is held to determine the rate or dividend for the next holding period. We can sell or continue to hold securities at par at each auction. In order for us to sell ARS, the auction needs to be successful whereby demand in the marketplace exceeds the supply. The length of each holding period is determined at the original issuance of the ARS. Typically, ARS holding periods range from 7 to 49 days. As of June 30, 2005, our ARS consist of $24,000,000 of perpetual securities and $54,950,000 with stated maturity dates ranging from 2022 to 2044 and reset dates of less than 5 months.

	June 30, 2005			
		Gross unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Certificates of deposit	$ 753,000	$ —	$ (3,094)	$ 749,906
Auction rate securities	78,950,000	—	—	78,950,000
Corporate debt securities	34,426,090	—	(31,600)	34,394,490
U.S. government debt securities	9,888,191	—	(10,191)	9,878,000
	$124,017,281	$ —	$ (44,885)	$123,972,396

	June 30, 2004			
		Gross unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Certificates of deposit	$ —	$ —	$ —	$ —
Auction rate securities	1,250,000	—	—	1,250,000
Corporate debt securities	—	—	—	—
U.S. government debt securities	—	—	—	—
	$ 1,250,000	$ —	$ —	$ 1,250,000

	December 31, 2004			
		Gross unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Certificates of deposit	$ —	$ —	$ —	$ —
Auction rate securities	12,000,000	—	—	12,000,000
Corporate debt securities	—	—	—	—
U.S. government debt securities	—	—	—	—
	$ 12,000,000	$ —	$ —	$ 12,000,000

As of June 30, 2005, the unrealized losses on the certificates of deposit, corporate debt securities and U.S. government securities were primarily caused by recent increases in interest rates. Based on an evaluation of the credit standing of each issuer, management believes it is probable that we will be able to collect all amounts due according to the contractual terms. We had no realized losses on sales of investment securities available-for-sale for the six months ended June 30, 2005.

5.5.6 Derivative Instruments

None.

5.5.7 Earnings Per Share Information

We calculated net loss per share in accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, *Earnings Per Share*. Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Upon the completion of our initial public offering, all of our previously outstanding preferred shares converted into 66,782,856 shares of our common stock. As a result of the issuance of these common shares, there is a lack of comparability in both the basic and diluted net loss per share amounts for the periods presented. In order to provide a more relevant measure of our operating results, an unaudited pro forma net loss per share calculation has been included. The shares used to compute unaudited pro forma basic and diluted net loss per share include the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as–if converted method as of the beginning of each period presented or the date of issuance, if later.

Historical and pro forma basic and diluted net loss per share was calculated as follows:

	Six months ended June 30,		Year ended December 31,
	2005	2004	2004
Historical			
Numerator:			
Net loss	$ (12,042,242)	$ (26,696,604)	$ (48,272,603)
Accretion to redemption value of redeemable convertible preferred stock	(19,689)	—	(78,756)
Deemed dividend resulting from beneficial conversion feature of Series C redeemable convertible preferred stock	—	—	(31,264,677)
Net loss applicable to common stockholders	$ (12,061,931)	$ (26,696,604)	$ (79,616,036)
Denominator:			
Weighted average common shares outstanding	79,558,668	500,000	500,000
Basic and diluted net loss per share	$ (0.15)	$ (53.39)	$ (159.23)
Pro Forma			
Pro forma net loss	$ (12,042,242)	$ (26,696,604)	$ (79,537,280)
Pro forma basic and diluted net loss per share	$ (0.13)	$ (0.96)	$ (1.85)
Shares used above	79,558,668	500,000	500,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock	12,913,812	27,446,401	42,443,281
Pro forma shares used to compute basic and diluted net loss per share	92,472,480	27,946,401	43,943,281
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation			
Preferred stock (as-converted)	—	39,115,000	66,782,856
Common stock warrants	13,356,572	7,823,000	13,356,572
Common stock options	1,482,500	1,420,000	1,550,000

5.5.8 Subsequent Events

5.5.8.1 *Subsequent Events as of June 30, 2005*

None

5.5.8.2 *Subsequent Events as of June 30, 2004*

Series C Preferred Stock Sale

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 $43,431,156, net of $1,390,771 of estimated issuance costs.

The Series C preferred stock was sold at a price per share below the anticipated initial public offering price contemplated by this prospectus. Accordingly, pursuant to Emerging Issues Task Force (“EITF”) Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, the Company will record 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 times 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 will increase the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share and will be reported as a charge to accumulated deficit and a credit to additional paid-in capital, with no net impact on total stockholders' equity.

On September 2, 2004, in conjunction with the sale of Series C preferred stock, the Company and its two founders amended the terms of their warrant agreements. In exchange for relinquishing any future anti-dilution rights, the number of underlying common shares that could be purchased under the terms of the warrants was increased and fixed at 12,856,572, up from 7,323,000. Since all of the warrants were previously variable, the Company will record stock-based compensation of $14,663,966 based on the estimated fair value of the underlying common stock on September 2, 2004, less any stock-based compensation previously recorded. Since the number of warrants became fixed at September 2, 2004, no additional compensation will be recorded.

5.5.8.3 *Subsequent Events as of December 31, 2004*

On February 4, 2005, we completed an initial public offering of 30,000,000 shares of common stock for proceeds to us of $104,486,895, net of underwriting discounts and commissions and offering expenses. In addition, on March 8, 2005, we closed the sale of an additional 1,573,000 shares of our common stock pursuant to the partial exercise, by our underwriters, of an over-allotment option which resulted in aggregate proceeds to us of $5,557,773.

In connection with our initial public offering, each share of preferred stock outstanding as of February 4, 2005 was automatically converted into common stock.

5.5.9 Changes in Capitalization

5.5.9.1 *New Issuance of Common Stock*

Date of Issuance	Form of Offering	Number of Shares Issued	Issued Price per Share	Capitalized Amount
February 4, 2005	Public Offering	30,000K Shares	400 Yen (approximately $3.88)	$104,487K
March 8, 2005	Private Offering	1,573K Shares	370 Yen (approximately $3.53)	$5,558K

5.5.9.2 *Conversion of Preferred Stock*

All of out outstanding shares of preferred stock have been converted into 66,782,856 shares of common stock upon the closing of our initial public offering on February 4, 2005.

Type of Preferred Stock	Issued Price per Share	Number of Preferred Stock Cancelled	Number of Common Stock Issued	Capitalized Amount
Series A Convertible Preferred Stock	$ 10.00	1,000,000 shares	10,000,000 shares	$ 10,000K*
Series B Convertible Preferred Stock	$ 100.00	291,150 shares	29,115,000 shares	$ 26,813K*
Series C Redeemable Convertible Preferred Stock	$ 1.62	27,667,856 shares	27,667,856 shares	$ 43,503K

* It was a conversion between different classes of stocks. As such, there was not any change in the total capital amounts due to the conversion.

6. Situations of Production, Order Receiving and Sale

We engage mainly in research and development and not in production and order receiving.

Revenues recorded with our main trade partners and the ratio against such sales are as follows:

Trade Partner	Six months ended June 30, 2005	Ratio	Six months ended June 30, 2004	Ratio	Year ended December 31, 2004	Ratio
Argenes Inc.	$ 33,887	100.0%	$ —	0.0%	$ 35,087	7.2%
Asahi Kasei Pharma Corp.	—	0.0%	186,960	100.0%	455,195	92.8%
Total	$ 33,887	100.0%	$ 186,960	100.0%	$ 490,282	100.0%