# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

# FORM 10-K

(Mark One)  ⊠ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECUR	RITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004	
OR	
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SEC	CURITIES EXCHANGE ACT OF 1934
For the <u>transition</u> period from to	
Commission file nur	nber <u>0-22245</u>
NEXMED, (Exact Name of Registrant as S	
Nevada (State or Other Jurisdiction of Incorporation or Organization)	<b>87-0449967</b> (I.R.S. Employer Identification No.)
350 Corporate Boulevard, R (Address of Principal Ex	
(609) 208-9 (Registrant's teleph	
Securities registered pursuant to	Section 12(b) of the Act:
<u>Title of Each Class</u> Common Stock, par value \$.001	Name of Exchange on Which Registered The NASDAQ National Market
Indicate by check mark whether the registrant (1) has filed all reports requirements for the past 90 days. Yes $\boxtimes$ No $\square$	· · · · · · · · · · · · · · · · · · ·
Indicate by check mark if disclosure of delinquent filers pursuant to location contained, to the best of registrant's knowledge, in definitive proxy or information any amendment to this Form 10-K.	
Indicate by check mark whether the registrant is an accelerated filer (as de	efined in Exchange Act Rule 12b-2) Yes ⊠ No □
As of March 11, 2005, 51,701,446 shares of the common stock, par val value of the common stock held by non-affiliates, based upon the last sale price \$87,814,906.	
DOCUMENTS INCORPORA	TED BY REFERENCE
Portions of our Proxy Statement to be delivered to our stockholders in cor "2005 Proxy Statement") are incorporated by reference into Part III of this Report.	nnection with the Company's 2005 Annual Meeting of Stockholders (the

# NEXMED, INC. INDEX TO ANNUAL REPORT ON FORM 10-K FILED WITH THE SECURITIES AND EXCHANGE COMMISSION

# YEAR ENDED DECEMBER 31, 2004

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#### PART I.

## ITEM 1. BUSINESS.

Some of the statements contained in this Report discuss future expectations, contain projections of results of operations or financial condition or state other "forward-looking" information. Those statements include statements regarding the intent, belief or current expectations of the Company and its management team. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to, those risks and uncertainties set forth under the heading "Factors That Could Affect Our Future Results" of Part I of this Report. In light of the significant risks and uncertainties inherent in the forward-looking statements included in this Report, the inclusion of such statements should not be regarded as a representation by us or any other person that our objectives and plans will be achieved.

#### General

NexMed, Inc. (the "Company," which may be referred to as "we," "us," or "our") is a pharmaceutical and medical technology company. We develop and commercialize therapeutic products based on proprietary delivery systems. We are currently focusing our efforts on new and patented pharmaceutical products based on a penetration enhancement drug delivery technology known as NexACT®, which may enable an active drug to be better absorbed through the skin.

#### **Products & Technologies**

We have been in existence since 1987. Since 1994, we have positioned ourselves as a pharmaceutical and medical technology company with a focus on developing and commercializing therapeutic products based on proprietary delivery systems.

We are currently focusing our efforts on new and patented topical pharmaceutical products based on a penetration enhancement drug delivery technology known as NexACT®, which may enable an active drug to be better absorbed through the skin. The NexACT® transdermal drug delivery technology is designed to enhance the absorption of an active drug through the skin, overcoming the skin's natural barrier properties and enabling high concentrations of the active drug to rapidly penetrate the desired site of the skin or extremity. Successful application of the NexACT® technology would improve therapeutic outcomes and reduce gastrointestinal or other systemic side effects that often accompany oral and injectable medications.

We intend to continue our efforts developing topical treatments including cream, lacquer, gel, patch and tape, based on the application of NexACT® technology to drugs: (1) previously approved by the FDA, (2) with proven efficacy and safety profiles, (3) with patents expiring or expired and (4) with proven market track records and potential.

We are focusing on our application of the NexACT® technology to Alprox-TD® cream for the treatment of male erectile dysfunction. We are exploring the application of the NexACT® technology to other drug compounds and delivery systems, and are in various stages of developing new topical treatments for female sexual arousal disorder, nail fungus, premature ejaculation, wound healing, arthritic pain, severe pain and the prevention of nausea and vomiting associated with post-operative surgical procedures and cancer chemotherapy.

In addition, we have been entertaining inquiries from other pharmaceutical companies that want to work with us utilizing the application of NexACT® technology to develop proprietary pharmaceutical products as new drug products or improved products in order to extend the life cycle of their existing products.

Alprox-TD® is an alprostadil-based cream treatment intended for patients with mild, moderate or severe erectile dysfunction. Our clinical studies have demonstrated that NexACT® enhancers promote the rapid absorption of alprostadil and improve clinical responses. In December 2002, we completed two pivotal Phase 3 studies for Alprox-TD®, which tested over 1,700 patients at 85 sites throughout the U.S. The two pivotal studies were randomized, double-blind, placebo-controlled, and designed to confirm the efficacy and safety of Alprox-TD® in patients with varying degrees of erectile dysfunction.

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On July 1, 2004, we entered into a license, supply and distribution agreement with Schering AG, Germany ("Schering"). This agreement provides Schering with exclusive commercialization rights to Alprox-TD® in approximately 75 countries including countries in Europe and the Middle East as well as South Africa, Australia and New Zealand. We will retain the intellectual property relating to Alprox-TD® and will manufacture and supply the product to Schering. Under the terms of this partnership, we will receive future milestone payments as well as a share of the revenue through transfer price payments based on the supply of Alprox-TD®. The overall financial terms are intended, depending upon performance levels, to approximate an equal sharing of the value of the product. We continue to engage in discussions with several pharmaceutical companies, and are engaged in draft contract negotiations with one of them, for the commercialization of Alprox-TD® in other markets, including the U.S. However, consummation of such additional arrangement(s) is subject to the negotiation of complex contractual relationships, and we may not be able to negotiate such agreement(s) on a timely basis, if at all, or on terms acceptable to us.

We have scheduled meetings during the first half of 2005 with various European regulatory authorities in connection with the Marketing Authorization Application (comparable to the New Drug Application in the U.S.) for Alprox-TD® in the European Union (EU) markets. The purpose of these meetings is to determine the requirements for filing and what additional studies, if any, may be needed to file the Marketing Authorization Application. The outcome of these meetings will allow us to better formulate and finalize our strategy for obtaining approval for Alprox-TD® in Europe. We also want to ensure that all European Union requirements are incorporated into the 12-month open-label safety study that we intend to initiate and conduct in the U.S.

Prior to filing a New Drug Application or the Marketing Authorization Application for Alprox-TD®, we will be required to initiate a new 12-month open-label safety study. We had previously initiated an open-label study, which was halted in November 2002 due to FDA concerns about results of our transgenic mice study. However, we have determined with the FDA that completion of the open-label study is not a prerequisite for our New Drug Application submission provided that the 12-month safety update on 100 patients is filed within four months after the New Drug Application submission. We are required to have three hundred patients complete six months of testing in the study at the time of New Drug Application submission, and 100 patients must complete the 12-month study prior to New Drug Application approval. Patient completion requirements may be different in the EU and other markets.

In late 2003, we met with the FDA to evaluate our Alprox-TD® New Drug Application package and to discuss possible product improvements. At that time, the FDA suggested that we include a transfer study of Alprox-TD® in female subjects as part of our New Drug Application submission. During the same meeting, we proposed to the FDA a new and improved formulation of Alprox-TD®, to include in our New Drug Application filing. The FDA has permitted us to switch to the new formulation if we conduct two bridging studies to confirm the efficacy of the new formulation. We continue to be engaged in discussions with the FDA concerning the regulatory plan for Alprox-TD® and intend to schedule a follow-up meeting in June or July 2005. We intend to obtain the FDA's concurrence with our plan prior to initiating the above-mentioned studies, which will be conducted concurrently with the open-label study and completed prior to the New Drug Application filing.

The timeframe for us to begin these studies largely depends on our ability to substantially pre-fund these studies through additional partnering agreements for Alprox-TD® or from other sources, and on regulatory concurrence. We believe that we will be able to file the New Drug Application in the U.S. and in Europe, approximately ten and six months, respectively, after the completion of patient enrollment for the open-label study. Pending the outcome of the meetings discussed above with European regulatory authorities in the first half of 2005, we anticipate that the timeframe for EU filings may be earlier than for U.S. filings. However, these timeframes may change if we encounter any delay in financing, clinical testing or regulatory review. If we are not able to successfully arrange financing through additional partnering agreements or from other sources in order to substantially pre-fund the studies described above or obtain timely and satisfactory regulatory review, we may be required to discontinue the development of Alprox-TD®. In addition, it is possible that we may not have successful clinical results or receive regulatory approval on a timely basis, if at all.

In April 2002, Alprox-TD® was launched in Hong Kong under the Befar® trademark. The product, which has been selling in China since October 2001, is manufactured and marketed by a local affiliate of Vergemont International Limited, our Asian licensee. We receive from our Asian licensee royalty payments and payments for manufacturing supplies in connection with the distribution of Befar® in China and may receive such payments in other Asian markets once Befar® is approved for marketing in such other markets. The sale of Befar® has been slower than anticipated for several reasons. The switching of distributors by our Asian licensee in China and in Hong Kong during 2003 significantly disrupted the sale of the product in the two markets. In addition, China has a limited number of patients who can afford erectile dysfunction treatments. In December 2002 and February 2003, our Asian licensee entered into licensing agreements for two of our NexACT®-based products with CJ Pharmaceuticals, one of the five largest pharmaceutical companies in South Korea. Its parent company, CJ Corporation, is a major conglomerate in South Korea. Pursuant to the terms of the agreement, CJ Pharmaceuticals will develop, file for regulatory approval, market and distribute Befar® and Femprox® in South Korea.

We are exploring the application of the NexACT® technology to other drug compounds and delivery systems. The furthest advanced of these products is Femprox®, which is an alprostadil-based cream product intended for the treatment of female sexual arousal disorder. We have completed one Phase 2 study for Femprox® and intend to continue with its U.S. clinical development pending the availability of additional partnering agreements. In November 2004, we completed enrollment of a 400-patient study for Femprox® in China. where the cost for conducting clinical studies is significantly lower than in the U.S. We anticipate that top-line results will be available during the second quarter of 2005. The clinical data from this study will be shared with potential co-development partners. In addition, the experience gained from this study will guide us in designing future U.S. studies.

In September 2004, we filed an Investigational New Drug application with the FDA for NM100060, our proprietary nail lacquer treatment for onychomycosis. We had previously completed overseas, a multi-center, randomized, placebo-controlled, parallel, blinded efficacy and safety study, which enrolled 120 patients with various severities of big toenail fungal infection. The study was designed to evaluate the dose-response relationship of the efficacy and safety of the NM100060 lacquer. The data suggest that all three tested doses of the NM100060 lacquer were well tolerated by the patients, and the primary efficacy rate was up to 60%. NM100060 is topically applied, and incorporates terbinafine, a currently marketed oral anti-fungal drug, with the NexACT® technology, which facilitates the permeation of the drug through the nail and into the nail bed. As a result, the NM100060 lacquer incorporates a significantly lower dose of less than 1% of the oral dose. On February 2, 2005, we announced the initiation of our U.S. Phase 1 testing which we anticipate will be completed during second quarter 2005. We anticipate that the combined data from this Phase 1 study along with studies that have been conducted overseas will allow us, with FDA concurrence, to move into Phase 3 trials by the end of 2005. We are in active discussions with potential pharmaceutical partners who are interested in co-developing the product with us for the U.S. and other international markets.

During the last 24 months, we have entered into a series of research and development agreements with Japanese pharmaceutical companies, to develop new topical treatments for different indications. These agreements provided for modest signing payments, followed by additional payments based on the achievement of certain milestones. We have completed all research and development work associated with these agreements and have recognized all related revenue and will recognize no further revenue related to these agreements. We anticipate that we will enter into additional research and development agreements during the next twelve months but we cannot assure you that we will be able to conclude any arrangement on a timely basis, if at all, or on terms acceptable to us.

# **Patents**

We have twelve U.S. patents either acquired or received out of a series of patent applications that we have filed in connection with our NexACT® technology and our NexACT®-based products under development, such as Alprox-TD®, Femprox®, and our non-steroidal anti-inflammatory cream. To further strengthen our global patent position on our proprietary products under development, and to expand the patent protection to other markets, we have filed under the Patent Cooperation Treaty, corresponding international applications for our issued U.S. patents and pending U.S. patent applications.

The following table identifies our twelve U.S. patents issued for NexACT® technology and/or our NexACT®-based products under development, and the year of expiration for each patent:

Patent Name	<b>Expiration Date</b>
Biodegradable Absorption Enhancers	2008
Biodegradable Absorption Enhancers	2009
Compositions and Methods for Amelioration of Human Female Sexual Dysfunction	2017
Topical Compositions for PGE1 Delivery	2017
Topical Compositions for Non-Steroidal Anti-Inflammatory Drug Delivery	2017
Medicament Dispenser	2019
Crystalline Salts of dodecyl 2-(N, N-Dimethylamino)	2019
Topical Compositions Containing Prostaglandin $\mathrm{E}_1$	2019
CIP: Topical Compositions Containing Prostaglandin E <sub>1</sub>	2019
Prostaglandin Composition and Methods of Treatment of Male Erectile Dysfunction	2020
CIP: Prostaglandin Composition and Methods of Treatment of Male Erectile Dysfunction	2020
Topical Stabilized Prostaglandin E Compound Dosage Forms	2023

In addition, we have over 200 International patents and U.S. and International patent applications pending.

# Research and Development.

Governmental authorities in the U.S. and other countries heavily regulate the testing, manufacture, labeling, advertising, marketing and distribution of our proposed products. None of our proprietary products under development, including the Alprox-TD® cream utilizing the NexACT® technology, has been approved for marketing in the U.S. Before we market any products we develop, we must obtain FDA and comparable foreign agency approval through an extensive clinical study and approval process.

The studies involved in the approval process are conducted in three phases. In Phase 1 studies, researchers assess safety or the most common acute adverse effects of a drug and examine the size of doses that patients can take safely without a high incidence of side effects. Generally, 20 to 100 healthy volunteers or patients are studied in the Phase 1 study for a period of several months. In Phase 2 studies, researchers determine the drug's efficacy with short-term safety by administering the drug to subjects who have the condition the drug is intended to treat, assess whether the drug favorably affects the condition, and begin to identify the correct dosage level. Up to several hundred subjects may be studied in the Phase 2 study for approximately 6 to 12 months, depending on the type of product tested. In Phase 3 studies, researchers further assess efficacy and safety of the drug. Several hundred to thousands of patients may be studied during the Phase 3 studies for a period lasting from 12 months to several years. Upon completion of Phase 3 studies, a New Drug Application is submitted to the FDA or foreign governmental regulatory authority for review and approval.

# Segment and Geographic Area Information

You can find information about our business segment and geographic areas of business in Note 13 of the Notes to Consolidated Financial Statements.

## **Employees**

As of March 1, 2005, we had 52 full time employees, 9 of whom have Ph.D degrees, 3 of whom are executive management and 36 of whom are engaged in research and development activities. We also rely on a number of consultants. None of our employees is represented by a collective bargaining agreement. We believe that we have a good relationship with our employees.

# **Executive Officers of the Registrant**

The Executive Officers of the Company are set forth below.

Name	Age*	Title	
Y. Joseph Mo, Ph.D.	57	Chairman of the Board of Directors, President and Chief Executive Officer	
Vivian H. Liu	43	Vice President, Chief Financial Officer and Secretary	
Kenneth F. Anderson	58	Vice President, Commercial Development	
* As of March 1, 2005			

Y. Joseph Mo, Ph.D., is, and has been since 1995, our Chief Executive Officer and President and Chairman and a member of our board of directors. His current term as member of our board of directors expires in 2005. Prior to joining us in 1995, Dr. Mo was President of Sunbofa Group, Inc., a privately-held investment consulting company. From 1991 to 1994, he was President of the Chemical Division, and from 1988 to 1994, the Vice President of Manufacturing and Medicinal Chemistry, of Greenwich Pharmaceuticals, Inc. Prior to that, he served in various executive positions with several major pharmaceutical companies, including Johnson & Johnson, Rorer Pharmaceuticals, and predecessors of SmithKline Beecham. Dr. Mo received his Ph.D. in Industrial and Physical Pharmacy from Purdue University in 1977.

Vivian H. Liu is, and has been, our Vice President of Corporate Affairs and Secretary since September 1995 and Chief Financial Officer since January 2004. In 1994, while we were in a transition period, Ms. Liu served as our Chief Executive Officer. From September 1995 to September 1997, Ms. Liu was our Treasurer. From 1985 to 1994, she was a business and investment adviser to the government of Quebec and numerous Canadian companies with respect to product distribution, technology transfer and investment issues. Ms. Liu received her MPA in International Finance from the University of Southern California and her BA from the University of California, Berkeley.

Kenneth F. Anderson is and has been, our Vice President of Commercial Development since November 2000. Mr. Anderson has extensive experience in the pharmaceutical industry. From 1997 to September 2000, Mr. Anderson was Senior Vice President, Director of Strategy and Business Development for Harrison Wilson & Associates, a consulting and marketing firm specializing in healthcare products and services. From 1980 to 1997, Mr. Anderson was at Bristol-Myers Squibb where he served in various management positions, including Senior Manager for Marketing and Director for Worldwide Business Development. From 1969 to 1979, Mr. Anderson was with Parke-Davis, a division of Warner Lambert. Mr. Anderson received his BA from Boston University.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission, and we have an Internet website address at <a href="http://www.nexmed.com">http://www.nexmed.com</a>. We make available free of charge on our internet website address our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also read and copy any document we file at the Securities and Exchange Commission's public reference room located at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-732-0330 for further information on the operation of such public reference room. You also can request copies of such documents, upon payment of a duplicating fee, by writing to the Securities and Exchange Commission at 450 Fifth Street, N.W., Washington, D.C. 20549 or obtain copies of such documents from the Securities and Exchange Commission's website at <a href="http://www.sec.gov">http://www.sec.gov</a>.

#### FACTORS THAT COULD AFFECT OUR FUTURE RESULTS

## RISKS RELATED TO THE COMPANY

#### We have a continuing need for additional financing.

Our cash position as of March 1, 2005 was approximately \$6.2 million, following successful completion of a private placement in December 2004 of common stock and warrants, yielding gross proceeds to us of approximately \$7 million. We have been actively seeking financing from the sale of equity or issuance of debt from private and public sources as well as from collaborative licensing and/or marketing arrangements with third parties, and since December 31, 2002, we have raised approximately \$42 million gross proceeds through the sale of Preferred Stock, the exercise of warrants to purchase shares of our common stock and the issuance by the Company of notes, Common Stock and warrants to purchase shares of Common Stock. Our anticipated cash requirements for Alprox-TD® through the anticipated New Drug Application filing, including completion of an open-label and other studies, will be approximately \$15 million. Initiation, but not completion of an open-label study is a prerequisite for our new drug application submission. There is no assurance that we will be successful in obtaining financing on acceptable terms, if at all. If additional financing cannot be obtained on reasonable terms, future operations may need to be scaled back or discontinued.

## We continue to incur operating losses.

Our current business operations began in 1994 and we have a limited operating history. We may encounter delays, uncertainties and complications typically encountered by development stage businesses. We have generated minimal revenues from the limited sales of Befar® in Asia and our existing research and development agreements with our Japanese partners, and have not marketed or generated revenues in the U.S. from our products under development. We are not profitable and have incurred an accumulated deficit of \$102,245,183 since our inception and through December 31, 2004. Our ability to generate revenues and to achieve profitability and positive cash flow will depend on the successful commercialization of our products currently under development. However, even if we eventually generate revenues from sales of our products currently under development, we expect to incur significant operating losses over the next several years. Our ability to become profitable will depend, among other things, on our (1) development of our proposed products, (2) obtaining of regulatory approvals of our proposed products on a timely basis and (3) success in manufacturing, distributing and marketing our proposed products.

## Our independent registered public accounting firm has doubt as to our ability to continue as a going concern.

As a result of our losses to date, expected losses in the future, limited capital resources and accumulated deficit, our independent registered public accounting firm has concluded that there is substantial doubt as to our ability to continue as a going concern, and accordingly, our independent registered public accounting firm has modified their report on our December 31, 2004 consolidated financial statements included herein in the form of an explanatory paragraph describing the events that have given rise to this uncertainty. These factors may make it more difficult for us to obtain additional funding to meet our obligations. Our continuation is dependent upon our ability to generate or obtain sufficient cash to meet our obligations on a timely basis and ultimately to attain profitable operations. We anticipate that we will continue to incur significant losses at least until successful commercialization of one or more of our products, and we may never operate profitably in the future.

## We will need significant additional funding to continue with our research and development efforts.

Our research and development expenses for the years ended December 31, 2004, 2003 and 2002, were \$10,684,477, \$8,439,340 and \$21,615,787, respectively. Since January 1, 1994, when we repositioned ourselves as a medical and pharmaceutical technology company, and through December 31, 2004 we have spent \$69,819,165 on research and development. While our expenses for research and development were significantly lower in 2003 than in 2002, they increased in 2004. Given our current level of cash reserves and low rate of revenue generation, we will not be able to fully advance the development of our products unless we raise additional cash through financing from the sale of our securities and/or through additional partnering agreements. If we are successful in entering into additional partnering agreements for our products under development, we may receive milestone payments, which will offset some of our research and development expenses.

As indicated above, our anticipated cash requirements for Alprox-TD® through the anticipated New Drug Application filing, including completion of an open-label and other studies, will be approximately \$15 million. Initiation, but not completion of an open-label study is a prerequisite for our New Drug Application filing.

We will also need significant funding to pursue our overall product development plans. In general, our products under development will require significant time-consuming and costly research and development, clinical testing, regulatory approval and significant additional investment prior to their commercialization. The research and development activities we conduct may not be successful; our products under development may not prove to be safe and effective; our clinical development work may not be completed; and the anticipated products may not be commercially viable or successfully marketed. Commercial sales of our products cannot begin until we receive final FDA approval. The earliest time for such final approval of the first product which may be approved, Alprox-TD®, is sometime in late 2006. We intend to focus our current development efforts on the Alprox-TD® cream treatment, which is in the late clinical development stage.

We currently have no sales force or marketing organization and will need, but may be unable, to attract or afford qualified or experienced marketing and sales personnel. In order to market Alprox-TD® in areas not covered under the Schering AG agreement and for our other proprietary products under development, additional marketing partner(s) will need to spend significant funds to inform potential customers, including third-party distributors, of the distinctive characteristics and benefits of our products. Our operating results and long term success will depend, among other things, on our ability to establish (1) successful arrangements with domestic and additional international distributors and marketing partners and (2) an effective internal marketing organization. We are currently engaged in discussions with several pharmaceutical companies regarding possible strategic marketing partnership(s) for the Alprox-TD® cream in markets not covered under the Schering AG agreement, including the U.S. However, in each case consummation of the transaction is subject to the negotiation of complex contractual relationships, and we may not be able to negotiate such agreements on a timely basis, if at all, or on terms acceptable to us.

## Pre-clinical and clinical trials are inherently unpredictable. If we do not successfully complete these trials, we will not be able to market our products.

Through pre-clinical studies and clinical trials, we must demonstrate that our products are safe and effective for their indicated uses. Results from pre-clinical studies and early clinical trials may not allow us to predict results in later-stage testing. Our future clinical trials may not demonstrate the safety and effectiveness of our products or may not result in regulatory approval to market our products. The failure of the FDA to approve our products for commercial sales will have a material adverse effect on our prospects.

#### Patents and intellectual property rights are important to us but could be challenged.

Proprietary protection for our pharmaceutical products is of material importance to our business in the U.S. and most other countries. We have sought and will continue to seek proprietary protection for our products to attempt to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. Our success may depend on our ability to (1) obtain effective patent protection within the U.S. and internationally for our proprietary technologies and products, (2) defend patents we own, (3) preserve our trade secrets, and (4) operate without infringing upon the proprietary rights of others.

While we have obtained patents and have several patent applications pending, the extent of effective patent protection in the U.S. and other countries is highly uncertain and involves complex legal and factual questions. No consistent policy addresses the breadth of claims allowed in or the degree of protection afforded under patents of medical and pharmaceutical companies. Patents we currently own or may obtain might not be sufficiently broad to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

There have been patents issued to others such as Vivus, Inc. and MacroChem Corporation on the use of alprostadil for the treatment of male or female sexual dysfunction. While we believe that our patents will prevail in any potential litigation, the holders of these competing patents could determine to commence a lawsuit against us and even prevail in any such lawsuit. Litigation could result in substantial cost to and diversion of effort by us, which may harm our business. In addition, our efforts to protect or defend our proprietary rights may not be successful or, even if successful, may result in substantial cost to us.

#### We depend upon third party manufacturers for our chemical manufacturing supplies.

We depend on third party chemical manufacturers for alprostadil, the active drugs in Alprox-TD® and in other NexACT®-based products under development, and for the supply of our NexACT® enhancers that are essential in the formulation and production of our products, on a timely basis and at satisfactory quality levels. If our validated third party chemical manufacturers fail to produce quality products on time and in sufficient qualities, our results would suffer, as we would encounter costs and delays in revalidating new third party suppliers.

#### We may not successfully validate our manufacturing facility for GMP compliance.

In 2002, we completed the construction of a 31,500 square foot industrial facility, located in East Windsor, New Jersey, which we are in the process of developing and validating as a manufacturing facility designed to meet the Good Manufacturing Practice (GMP) standards as required by the FDA. We anticipate that our manufacturing facility will have the capacity to meet our anticipated needs for full-scale commercial production. However, we are initially utilizing the facility to manufacture Alprox-TD® and other NexACT®-based products under development for continuing clinical testing purposes and at the same time validating the facility for GMP compliance, which is a requirement for our new drug application filing with the FDA. If we do not successfully pass the Pre-Approved Inspection conducted by the FDA, our new drug application filing will be delayed.

#### We face severe competition.

We are engaged in a highly competitive industry. We expect competition from numerous existing companies, including large international enterprises, and others entering the industry. Most of these companies have greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources. Acquisitions of competing companies by large pharmaceutical or healthcare companies could further enhance such competitors' financial, marketing and other resources. Competitors may complete clinical trials, obtain regulatory approvals and commence commercial sales of their products before we could enjoy a significant competitive advantage. Products developed by our competitors may be more effective than our products.

Certain treatments for erectile dysfunction, such as needle injection therapy, vacuum constriction devices, penile implants, transurethral absorption and oral medications, currently exist, have been approved for sale in certain markets and are being improved. Currently known products for the treatment of erectile dysfunction developed or under development by our competitors include the following: (1) Caverject®, Pfizer, Inc.'s needle injection therapy; (2) Viagra®, Pfizer, Inc.'s oral product to treat erectile dysfunction; (3) Cialis®, an oral formulation marketed in the U.S. through a joint venture between ICOS and Eli Lilly & Co.; (4) Levitra®, an oral medication marketed through a collaborative effort of Schering-Plough and GlaxoSmithKline, Inc. and (5) Muse®, Vivus, Inc.'s device for intra-urethral delivery of a suppository containing alprostadil. In addition, products currently under development include the following: (1) Topiglan®, a topical treatment containing alprostadil based on a proprietary drug delivery system under development by MacroChem Corporation; (2) PT-141, an intra-nasal treatment containing a new peptide under development by Palatin Technologies; and (3) an intranasal apomorphine treatment under development by Nastech.

# We have been the subject of several lawsuits and may be subject of potential product liability and other claims, creating risk and expense.

A lawsuit was filed with the Superior court of New Jersey on April 1, 2003 by a former employee against the Company for a \$800,000 bonus amount that he believes he should have received upon completion of the construction of the Company's East Windsor manufacturing facility. The Company has engaged counsel to defend its position. The Company intends to defend itself vigorously against this claim and believes it has a valid defense; however, the case is still in the preliminary stages and the likely outcome cannot be predicted, nor can a reasonable estimate of the amount of loss, if any, be made.

We are also exposed to potential product liability risks inherent in the development, testing, manufacturing, marketing and sale of human therapeutic products. Product liability insurance for the pharmaceutical industry is extremely expensive, difficult to obtain and may not be available on acceptable terms, if at all. We currently have liability insurance to cover claims related to our products that may arise from clinical trials, with coverage of \$1 million for any one claim and coverage of \$3 million in total, but we do not maintain product liability insurance and we may need to acquire such insurance coverage prior to the commercial introduction of our products. If we obtain such coverage, we have no guarantee that the coverage limits of such insurance policies will be adequate. A successful claim against us if we are uninsured, or which is in excess of our insurance coverage, if any, could have a material adverse effect upon us and on our financial condition.

# Our Stock may be delisted from Nasdaq, which may make it more difficult for you to sell your shares.

Currently, our common stock trades on the Nasdaq National Market. NASD Marketplace Rule 4450 provides that a company must comply with continuing listing criteria to maintain its Nasdaq listing. Included in such criteria is a minimum bid price per share of \$1.00. Failure to maintain such price for a period of time and beyond a grace period could lead to delisting from the Nasdaq National Market.

If we were to be delisted from the Nasdaq National Market, our common stock would be listed on the Nasdaq SmallCap Market, assuming we meet those listing requirements. If we failed to meet the Nasdaq SmallCap listing requirements, our stock would be considered a penny stock under regulations of the Securities and Exchange Commission and would therefore be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of the common stock and your ability to sell our securities in the secondary market. In addition, if we fail to obtain a SmallCap listing, we will be subject to cash penalties under the Investor Rights Agreement and other investor rights agreements to which we are a party until a listing is obtained.

## INDUSTRY RISKS

#### We are subject to numerous and complex government regulations which could result in delay and expense.

Governmental authorities in the U.S. and other countries heavily regulate the testing, manufacture, labeling, distribution, advertising and marketing of our proposed products. None of our proprietary products under development has been approved for marketing in the U.S. Before we market any products we develop, we must obtain FDA and comparable foreign agency approval through an extensive clinical study and approval process.

Our failure to obtain requisite governmental approvals for our products under development in a timely manner or at all would delay or preclude us from licensing or marketing our products or limit the commercial use of our products, which could adversely affect our business, financial condition and results of operations.

Because we intend to sell and market our products outside the U.S., we will be subject to foreign regulatory requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements. These requirements vary widely from country to country. Our failure to meet each foreign country's requirements could delay the introduction of our proposed products in the respective foreign country and limit our revenues from sales of our proposed products in foreign markets.

Successful commercialization of our products may depend on the availability of reimbursement to the consumer from third-party healthcare payers, such as government and private insurance plans. Even if we succeed in bringing one or more products to market, reimbursement to consumers may not be available or sufficient to allow us to realize an appropriate return on our investment in product development or to sell our products on a competitive basis. In addition, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to governmental controls. In the U.S., federal and state agencies have proposed similar governmental control and the U.S. Congress has recently considered legislative and regulatory reforms that may affect companies engaged in the healthcare industry. Pricing constraints on our products in foreign markets and possibly in the U.S. could adversely affect our business and limit our revenues.

#### We are vulnerable to volatile market conditions.

The market prices for securities of biopharmaceutical and biotechnology companies, including ours, have been highly volatile. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, future announcements, such as the results of testing and clinical trials, the status of our relationships with third-party collaborators, technological innovations or new therapeutic products, governmental regulation, developments in patent or other proprietary rights, litigation or public concern as to the safety of products developed by us or others and general market conditions, concerning us, our competitors or other biopharmaceutical companies, may have a significant effect on the market price of our common stock.

## RISKS RELATED TO OWNING OUR COMMON STOCK

## We do not expect to pay dividends on our common stock in the foreseeable future.

Although our shareholders may receive dividends, if as and when declared by our board of directors, we do not intend to pay dividends on our Common Stock in the foreseeable future. Therefore, you should not purchase our Common Stock if you need immediate or future income by way of dividends from your investment.

# We may issue additional shares of our capital stock that could dilute the value of your shares of Common Stock.

We are authorized to issue 90,000,000 shares of our capital stock, consisting of 80,000,000 shares of our Common Stock and 10,000,000 shares of our preferred stock, of which 1,000,000 are designated as Series A Junior Participating Preferred Stock and 800 are designated as Series B 8% Cumulative Convertible Preferred Stock. As of March 11, 2005, 51,701,446 shares of our Common Stock were issued and outstanding and 17,891,169 shares of our Common Stock were issued upon the exercise of outstanding options, warrants, or other convertible securities (including warrants and convertible notes held by certain selling shareholders). There were no shares of Preferred Stock outstanding at March 11, 2005. In light of our need for additional financing, we may issue authorized and unissued shares of Common Stock at below current market prices or additional convertible securities that could dilute the earnings per share and book value of your shares of our Common Stock.

In addition to provisions providing for proportionate adjustments in the event of stock splits, stock dividends, reverse stock splits and similar events, certain warrants provide (with certain exceptions) for an adjustment of the exercise price if we issue shares of common stock at prices lower than the exercise price or the then prevailing market price. This means that if we need to raise equity financing at a time when the market price for our common stock is lower than the exercise price, or if we need to provide a new equity investor with a discount from the then prevailing market price, then the exercise price will be reduced and the dilution to shareholders increased.

## ITEM 2. PROPERTIES.

We currently have our principal executive offices and laboratories in Robbinsville, NJ. We lease approximately 24,000 square feet of space for approximately \$25,500 per month pursuant to a lease which expires in March 2006. We also lease approximately 5,000 square feet of laboratory space in Monmouth Junction, NJ for approximately \$14,000 per month pursuant to a lease which expires in May 2006.

We own our 31,500 square foot manufacturing facility in East Windsor, New Jersey. We purchased the facility for \$2.2 million and have invested approximately \$7.2 million for construction, equipment and FDA GMP development.

NexMed International Limited subleases 1,000 square feet of office space in Hong Kong for approximately \$3,000 per month pursuant to a month-to-month arrangement.

#### ITEM 3. LEGAL PROCEEDINGS.

A lawsuit was filed with the Superior court of New Jersey on April 1, 2003 by a former employee against the Company for a \$800,000 bonus amount that he believes he should have received upon completion of the construction of the Company's East Windsor manufacturing facility. The Company has engaged counsel to defend its position. The Company intends to defend itself vigorously against this claim and believes it has a valid defense; however, the case is still in the preliminary stages and the likely outcome cannot be predicted, nor can a reasonable estimate of the amount of loss, if any, be made.

# ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders during the fourth quarter of 2004.

## PART II.

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our Common Stock is traded on the NASDAQ National Market System ("NASDAQ") under the symbol "NEXM."

The following table sets forth the range of the high and low sales prices as reported by NASDAQ for each quarter from January 1, 2003 to December 31, 2004.

	Price of	Common Stock (\$)
	High	Low
<u>2003</u>		<del></del> -
First Quarter	2.20	0.75
Second Quarter	5.25	1.09
Third Quarter	4.83	2.56
Fourth Quarter	5.65	3.35
<u>2004</u>		
First Quarter	4.70	2.20
Second Quarter	3.45	1.46
Third Quarter	2.44	1.25
Fourth Quarter	1.69	1.20

On March 11, 2005, the last reported sales price for our Common Stock on NASDAQ was \$1.27 per share, and we had 250 holders of record of our Common Stock.

# Dividends

We have never paid cash dividends on our common stock and do not have any plans to pay cash dividends in the foreseeable future. Our board of directors anticipates that any earnings that might be available to pay dividends will be retained to finance our business.

#### ITEM 6. SELECTED FINANCIAL DATA.

I..... Statement Date

The following selected financial information is qualified by reference to, and should be read in conjunction with, the Company's consolidated financial statements and the notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained elsewhere herein.

Income Statement Data						
		2004	2003	2002	2001	2000
Revenue						
Product sales and royalties	\$	9,519	\$ 6,206	\$ 63,417	\$ 68,089	0
Research and development fees	\$	349,850	\$ 104,537	\$ 84,611	0	0
Net Loss	\$	(17,023,648)	\$ (17,233,566	) \$ (27,641,519)	\$ (16,174,861)	\$ (8,720,553)
Basic and Diluted Loss per Share		(\$0.39)	\$ (0.60	) \$ (1.03)	\$ (0.63)	\$ (0.40)
Weighted Average Common Shares Outstanding Used for Basic and Diluted Loss per Share		43,603,546	33,649,774	26,937,200	25,486,465	21,868,267
Balance Sheet Data	Г	December 31, 2004	December 31, 2003	December 31, 2002	December 31, 2001	December 31, 2000
Total Assets	\$	20,272,661	\$ 23,133,679	\$ 14,140,127	\$ 27,314,713	\$ 39,989,682
Total Long Term Liabilities	\$	6,801,826	\$ 7,335,877	\$ 5,782,518	\$ 724,577	\$ 0
Stockholders' Equity	\$	11.401.285	\$ 12,723,408	\$ 3.223.492	\$ 24.107.865	\$ 38.744.175

We do not have any off-balance sheet arrangements.

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

#### General

We are focusing our application of the NexACT® technology to Alprox-TD® cream for the treatment of male erectile dysfunction. We have explored the application of the NexACT® technology to other drug compounds and delivery systems, and are in various stages of developing new treatments for female sexual arousal disorder, nail fungus, premature ejaculation, wound healing, arthritic pain, severe pain, and the prevention of nausea and vomiting associated with post-operative surgical procedures and cancer chemotherapy.

We intend to pursue our research, development, and execute a business strategy with the goal of achieving a level of development sufficient to enable us to attract potential strategic partners with resources sufficient to further develop and market our proprietary products both domestically and internationally.

# **Liquidity and Capital Resources**

We have experienced net losses and negative cash flow from operations each year since our inception. Through December 31, 2004, we had an accumulated deficit of \$102,245,183. Our operations have principally been financed through private placements of equity securities and debt financing. Funds raised in past periods should not be considered an indication of our ability to raise additional funds in any future periods.

Pursuant to a Common Stock and Warrant Purchase Agreement dated December 17, 2004, we raised over \$7 million in gross proceeds. We sold 5,495,310 shares of our common stock at \$1.28 per share. The investors received five-year warrants to purchase 2,198,126 shares of common stock, exercisable beginning six months after closing at a price of \$1.47 per share. In addition, the investors also received one-year warrants to purchase 549,536 shares of common stock, exercisable at a price of \$2.00 per share. The proceeds from this financing are being used for general corporate purposes and for our product development programs based on the NexACT® technology.

As a result of our losses to date, expected losses in the future, limited capital resources and accumulated deficit, our independent registered public accounting firm has concluded that there is substantial doubt as to our ability to continue as a going concern for a reasonable period of time, and have modified their report in the form of an explanatory paragraph describing the events that have given rise to this uncertainty. These factors may make it more difficult for us to obtain additional funding to meet our obligations. Our continuation is based on our ability to generate or obtain sufficient cash to meet our obligations on a timely basis and ultimately to attain profitable operations. We anticipate that we will continue to incur significant losses at least until successful commercialization of one or more of our products. There can be no assurance that we can operate profitably in the future.

At December 31, 2004, we had cash and cash equivalents, and marketable securities and short-term investments of approximately \$9.13 million as compared to \$10.98 million at December 31, 2003. To date, we have spent approximately \$66 million on the Alprox-TD® development program, and anticipate that we will spend approximately an additional \$15 million to complete the clinical program and file the new drug application for Alprox-TD®. During 2004, we expended approximately \$15.7 million in cash, which consisted of a \$1.3 million to a contract research organization for set-up and initiation costs for the planned clinical studies for Alprox-TD®, approximately \$500,000 paid to employees for the 2003 bonuses accrued in December of 2003, approximately \$2.1 million in out of pocket development costs related to other NexACT®-based products, including approximately \$1.9 million related to the NM100060 lacquer, approximately \$540,000 in legal fees related to ongoing lawsuits as well as approximately \$520,000 in professional fees related to additional compliance activities mandated by the Sarbanes Oxley Act of 2002, as well as our fixed monthly overhead costs of approximately \$900,000 per month. We project that our cash reserves are sufficient to sustain operations for 5 months at our current expenditure level, which includes fixed monthly overhead expenses and the projected out of pocket project costs related to NexACT®-based products other than Alprox-TD®. We anticipate that our monthly rate of cash expenditures will increase significantly upon initiating the planned clinical studies for Alprox-TD® and the NM100060 lacquer. The timeframe for us to begin these studies largely depends on our ability to obtain financing through additional partnering agreements for Alprox-TD® and the NM100060 lacquer or from other sources, and on regulatory review.

At December 31, 2004, we recorded significantly less non-cash interest expense charges from convertible notes than at December 31, 2003, since in 2003 we wrote-off the discount attributable to the \$5 million convertible notes converted to common stock in 2003.

At December 31, 2004 we recorded significantly higher non-cash compensation expense as compared to 2003. The increase is largely attributable to our CEO's 2003 bonus of approximately \$400,000 that was paid in stock in 2004.

At December 31, 2004, we had \$277,660 in payroll related liabilities as compared to \$1,273,303 at December 31, 2003. The decrease is attributable to 2003 bonuses of \$1,074,400 that were accrued in 2003 but paid in 2004. We did not approve bonuses for 2004, and therefore there are no bonuses accrued at December 31, 2004.

At December 31, 2004, we had no deferred revenue as compared to \$128,708 at December 31, 2003. The decrease is the result of our recognition of all of the revenue deferred at December 31, 2003 related to our research and development projects for our Japanese partners. We have completed all research and development work associated with these agreements and have recognized all related revenue.

We have spent approximately \$9.4 million in total for the land, building, manufacturing and lab equipment, and GMP development as related to our East Windsor manufacturing facility and estimate that an additional \$2 million, approximately, will be spent prior to the FDA pre-approval inspection for the facility.

We lease office space and research facilities under operating lease agreements expiring through 2007. We also lease equipment from GE Capital under capital leases expiring through 2006 (Note 6 of the Financial Statements). The following table summarizes our contractual obligations and the periods in which payments are due as of December 31. 2004:

		Less than	1 - 3	3 - 5		More than
Contractual Obligations	Total	1 year	years	years		5 years
Long-term debt *	\$ 6,000,000	\$ 0	\$ 6,000,000	\$	0 \$	0
Capital lease obligations	931,915	690,816	241,099		0	0
Operating leases	572,301	469,378	102,923		0	0
Purchase obligations **	11,541,922	2,560,859	8,981,063		0	0
Other long-term liabilities***	2,625,000	0	 0		0	2,625,000
Total	\$ 21,671,138	\$ 3,721,053	\$ 15,325,085	\$	0 \$	2,625,000

- \* Long-term debt consists of two notes that are convertible to common stock at the option of the noteholders.
- \*\* Purchase obligations consist of clinical research agreements that can be cancelled at any time with thirty days notice. The penalty for our cancellation of one of the agreements totaling \$10,246,000 is 10% of the oustanding contract amount at the time of cancellation.
- \*\*\* Represents the fully vested payments to be made according to a deferred compensation agreement. The partially vested present value of \$568,000 of this obligation is reflected on our balance sheet in other long term liabilities.

In February 2001, we entered into a financial arrangement with GE Capital Corporation for a line of credit, which provided for the financing of up to \$5 million of equipment and expired in March 2002. As of March 31, 2002, we had financed \$1,113,459 of equipment purchases under this GE credit line, and as of December 31, 2004, there was an outstanding balance due GE of \$57,832 under this facility which is payable in monthly installments through various dates in 2005 and which is reflected in the above table under capital lease obligations.

In January 2002, GE approved a new credit line, which provided for the financing of up to \$3 million of equipment and expired on December 31, 2002. We accessed \$1,111,427 of this credit line, and as of December 31, 2004, there was an outstanding balance due GE of \$375,571 under the January 2002 facility, which is payable in 42 monthly installments from the date of take-down and which is reflected in the above table under capital lease obligations.

In July 2003, GE approved a new credit line, which expired in July 2004 and provided for the financing of up to \$1.85 million of equipment. We accessed \$738,731 of this credit line, and as of December 31, 2004, there was an outstanding balance due GE of \$444,473 under the July 2003 facility which is payable in 36 monthly installments from the date of take-down and which is reflected in the above table under capital lease obligations.

# Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

# **Critical Accounting Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. Note 2 in the Notes to the Consolidated Financial Statements, includes a summary of the significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The preparation of these financial statements requires our management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Our accounting policies affect our more significant judgments and estimates used in the preparation of its financial statements. Actual results could differ from these estimates. The following is a brief description of the more significant accounting policies and related estimate methods that we follow:

Income Taxes - In preparing our financial statements, we make estimates of our current tax exposure and temporary differences resulting from timing differences for reporting items for book and tax purposes. We recognize deferred taxes by the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In addition, valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

<u>Critical Estimate:</u> In consideration of our accumulated losses and lack of historical ability to generate taxable income to utilize our deferred tax assets, we have estimated that we will not be able to realize any benefit from our temporary differences and have recorded a full valuation allowance. If we become profitable in the future at levels which cause management to conclude that it is more likely than not that we will realize all or a portion of the net operating loss carry-forward, we would immediately record the estimated net realized value of the deferred tax asset at that time and would then provide for income taxes at a rate equal to our combined federal and state effective rates, which would be approximately 40% under current tax laws. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Long-lived assets -- We review for the impairment of long-lived assets whenever events or circumstances indicate that the carrying amount of an asset may not be 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. If such assets are considered impaired, the amount of the impairment loss recognized is measured as the amount by which the carrying value of the asset exceeds the fair value of the asset, fair value being determined based upon discounted cash flows or appraised values, depending on the nature of the asset. We have not identified any such impairment losses.

<u>Critical Estimate</u>: Estimated undiscounted future cash flows are based on sales projections for our products under development for which the long-lived assets are used. In 2004, we performed a review for impairment of our manufacturing facility based on projections of sales of our product candidates, for which the facility is anticipated to be ultimately utilized. Overestimating the future cash flows resulting from the commercialization of Alprox TD<sup>-</sup> may lead to overstating the carrying value of the manufacturing facility by not identifying an impairment loss.

Revenue recognition -- Revenues from product sales are recognized upon delivery of products to customers, less allowances for returns and discounts. Royalty revenue is recognized upon the sale of the related products, provided the royalty amounts are fixed or determinable and the amounts are considered collectible. Revenues earned under research and development contracts are recognized in accordance with the cost-to-cost method outlined in Staff Accounting Bulletin No. 101, as amended, whereby the extent of progress toward completion is measured on the cost-to-cost basis; however, revenue recognized at any point will not exceed the cash received. If the current estimates of total contract revenue and contract cost indicate a loss, a provision for the entire loss on the contract would be made. All costs related to these agreements are expensed as incurred and classified within "Research and development" expenses in the Consolidated Statements of Operations and Comprehensive Loss. Research and development expenses include costs directly attributable to the conduct of our research and development, including salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research and development fee agreements, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drugs for use in research, pre-clinical and clinical development, and the allocable portion of facility costs.

<u>Critical Estimate</u>: In calculating the progress made toward completion of a research contract, we must compare costs incurred to date to the total estimated cost of the project. We estimate the cost of any given project based on our past experience in product development as well as the past experience of our research staff in their areas of expertise. Underestimating the total cost of a research contract may cause us to accelerate the revenue recognized under such contract. Conversely, overestimating the cost may cause us to delay revenue recognized.

Stock based compensation -- In preparing our financial statements, we must calculate the value of stock options issued to employees as well as non-employee contractors. The fair value of each option and warrant is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model is a generally accepted method of estimating the value of stock options and warrants.

<u>Critical Estimate</u>: The Black-Scholes option pricing model requires us to estimate the Company's dividend yield rate, expected volatility and risk free interest rate over the life of the option. Inaccurately estimating any one of these factors may cause the value of the option to be under or over estimated. See Note 7 of the Consolidated Financial Statements for the current estimates used in the Black -Scholes pricing model.

# Comparison of Results of Operations between the Years Ended December 31, 2004 and 2003.

Revenues. We recorded revenues of \$359,369 during the twelve months of operations in 2004 as compared to \$110,743 during the same period in 2003. The revenue consisted of \$9,519 and \$6,206, respectively, in royalties on sales of Befar® in Hong Kong and China received from our Asian licensee and \$349,850 and \$104,537, respectively, of revenue recognized on our research and development agreements with Japanese pharmaceutical companies. The increase in research and development fee revenue in 2004 is the result of the completion in 2004 of all research and development work associated with these agreements and the recognition of all related revenue.

Research and Development Expenses. Our research and development expenses for 2004 and 2003 were \$10,684,477 and \$8,439,340 respectively. Research and development expenses included \$2,811,523 attributable to Alprox-TD® in 2004, and \$2,279,848 attributable to NM100060 with the balance attributable to other NexACT® technology based products and indirect overhead related to research and development, as compared to \$2,885,020 for Alprox-TD® and \$393,858 for NM 100060 during the same period in 2003. There was a significant increase in expenses related to NM 100060 as preclinical activity increased with the filing of the investigational new drug application in 2004 and with the planned clinical trials to begin in 2005. We anticipate that, assuming available funding, total research and development spending in 2005 will increase significantly with the completion of the remaining Alprox-TD clinical studies which will cost approximately \$15 million and the anticipated filing of the new drug application for Alprox-TD in 2006; the increase in efforts and resources on the application of the NexACT® technology to other drug compounds and delivery systems for the development of new products including the planned clinical development program for NM 100060; and the filing of investigational new drug applications for some of the NexACT®-based products under development which would include the initiation of Phase 1 and 2 clinical studies in the U.S.

General and Administrative Expenses. Our general and administrative expenses were \$6,979,730 in 2004 as compared to \$5,900,569 in 2003. The increase is largely attributable to increased legal fees related to lawsuits as well as professional fees related to additional compliance activities mandated by the Sarbanes Oxley Act of 2002. Additionally, we have been steadily increasing expenses since the second half of 2003 in order to return to the general and administrative support levels that are necessary to operate the Company under the scaled up Alprox-TD® and other NexACT®-based products development programs. We anticipate that General and Administrative expenses in 2005 will remain consistent with 2004 expenses.

Other income (expense). Other income was \$82,271 during 2004 as compared to other expense of \$152,867 during the same period in 2003. The other income for 2004 consists of a one-time payment that the Company received upon cancellation of a research and development agreement with a Japanese pharmaceutical company partially offset by a loss on the sale of marketable securities. The 2003 expense was attributable to the sale at a loss of marketable securities and the disposition of equipment at a loss in order to generate additional cash.

Interest Expense. We recognized \$425,128 in interest expense in 2004 as compared to \$3,159,338 in interest expense during 2003. The significant decrease is the result of a decrease in the amortization of note discounts related to our convertible notes.

Net Loss. The net loss was \$17,023,648 and \$17,233,566 in 2004 and 2003, respectively. The slight decrease is primarily attributable to increased revenues and a significant decrease in interest expense offset by an increase in research and development expenses related to our product development programs for Alprox-TD® and NM100060 as well as increased legal fees related to lawsuits and increased professional fees related to additional compliance activities mandated by the Sarbanes Oxley Act of 2002. We anticipate that net loss in 2005 will increase significantly with the increased expenses related to clinical activities and new drug application filing for Alprox-TD®, and planned development activities for other NexACT®-based products under development including the clinical development program for NM 100060.

Net Loss applicable to Common Stock. The net loss applicable to common stock was \$17,023,648 or \$0.39 per share for 2004 as compared to \$20,351,410 or \$0.60 per share for 2003. The decrease in net loss applicable to common stock is primarily attributable to a deemed dividend related to the beneficial conversion feature of our preferred stock issued in 2003 as well as an increase in the total number of weighted average shares outstanding from 33,649,744 to 43,603,546.

#### Comparison of Results of Operations between the Years Ended December 31, 2003 and 2002.

Revenues. We recorded revenues of \$110,743 during the twelve months of operations in 2003 as compared to \$148,028 during the same period in 2002. The 2003 revenues consisted of \$6,206 in royalties on sales received from our Asian licensee and \$104,537 of revenue recognized on our research and development agreements with Japanese pharmaceutical companies. During 2003, we received an additional \$128,708 from research and development agreements with Japanese pharmaceutical companies, which we recognized as revenues in 2004.

Cost of Products Sold. Our cost of products sold was nil and \$27,030 in 2003 and 2002, respectively and is attributable to our cost for the manufacturing supplies sold to our Asian licensee for the production of Befar in China. Our Asian licensee had a sufficient inventory of the manufacturing supplies during 2003.

Research and Development Expenses. Our research and development expenses for 2003 and 2002 were \$8,439,340 and \$21,615,787, respectively. Research and development expenses attributable to Alprox-TD® and Femprox® for 2003 were \$2,885,020 and \$35,699, respectively with the balance attributable to NexACT® technology based products and indirect overhead related to research and development, as compared to approximately \$15,835,000 and \$642,000, respectively in 2002. The significant decrease was attributable to the completion of the costly Phase 3 trials for Alprox-TD® in December 2002 and a significant reduction in expenses and non-essential personnel under our cash conservation program implemented in November 2002. The significant decrease in research and development expenses was partially offset by an expense of \$418,933 in 2003 for bonuses to be paid in 2004 to employees. Research and development expenses include all costs associated with our research and development agreements.

General and Administrative Expenses. Our general and administrative expenses were \$5,900,569 in 2003 as compared to \$6,065,347 during 2002. The decrease was primarily attributable to the significant reduction in expenses and non-essential personnel under our cash conservation program implemented in November 2002 which was offset by an expense of \$655,467 in 2003 for bonuses to be paid in 2004 to employees of which approximately \$400,000 was to be paid in the Company's common stock.

Other expense. Other expense was \$152,867 in 2003 as compared to \$81,008 in 2002. The increase was attributable to a loss on the disposition of property and equipment of \$114,542. In 2003, we sold some lab equipment that was no longer in use in order to generate some additional cash inflow.

Interest Expense. We recognized \$3,159,338 in interest expense during 2003 as compared to \$384,286 during 2002. The significant increase in interest expense was a result of an increase in interest expense charges from convertible notes, including the write-off of the discount attributable to the conversion of \$5 million of our convertible notes into common stock in 2003, and increased borrowings under our GE Capital facility.

Net Loss. The net loss was \$17,233,566 for 2003, as compared to \$27,641,519 for 2002. The significant decrease was primarily attributable to the completion of the two pivotal Phase 3 trials for Alprox-TD® in December 2002 and a significant reduction in expenses and non-essential personnel under our cash conservation program implemented in November 2002.

Net Loss applicable to Common Stock. The net loss applicable to common stock was \$20,351,410 or \$0.60 per share for 2003, as compared to \$27,641,519 or \$1.03 per share for 2002. The decrease in net loss applicable to common stock was primarily attributable to decreased spending resulting from the completion of the two pivotal Phase 3 trials for Alprox-TD® in December 2002 and a significant reduction in expenses and non-essential personnel under our cash conservation program implemented in November 2002. The decrease in operating expenses was partially offset by the 2003 bonuses and the deemed dividend related to the beneficial conversion feature of the preferred stock as discussed in Note 11 of the consolidated financial statements.

# **Quarterly Results**

The following table sets forth selected unaudited quarterly financial information for the years ended December 31, 2003 and 2004. The operating results are not necessarily indicative of results for any future period.

# For the Three Months Ended

	Ma	rch 31, 2004	June 30, 2004	:	September 30, 2004	December 31, 2004
Total Revenues	\$	104,199	\$ 189,266	\$	63,457	\$ 2,447
Loss from Operations		(\$3,890,187)	(\$4,045,544)		(\$4,632,220)	(\$4,736,887)
Net Loss		(\$3,981,566)	(\$4,047,634)		(\$4,716,253)	(\$4,278,195)
Basic & Diluted Loss Per Share	\$	(0.10)	\$ (0.10)	\$	(0.10)	\$ (.09)
		March 31, 2003	June 30, 2003		September 30, 2003	December 31, 2003
Total Revenues	\$	,	\$ <b>June 30, 2003</b> 971	\$		\$ ,
Total Revenues Loss from Operations	\$	2003	\$ 	\$	2003	\$ 2003
	\$	<b>2003</b> 1,713	\$ 971	\$	<b>2003</b> 64,552	\$ <b>2003</b> 43,507

# ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not hold derivative financial investments, derivative commodity investments, engage in foreign currency hedging or other transactions that expose us to material market risk.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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#### Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of NexMed, Inc.:

We have completed an integrated audit of NexMed, Inc.'s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

## Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of NexMed, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and negative cash flows from operations, has limited capital resources and expects to incur future losses. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP New York, New York March 15, 2005

		Decem	ber 3	1,
Assets		2004		2003
Current assets				
Cash and cash equivalents	\$	7,747,285	\$	10,479,214
Marketable securities and short term investments		1,384,000		501,204
Note receivable		_		48,341
Prepaid expenses and other current assets		1,399,514		1,482,426
Total current assets		10,530,799		12,511,185
Fixed assets, net		9,714,450		10,583,733
Debt issuance cost, net of accumulated amortization of \$12,139 and \$794	_	27,412		38,761
Total assets	<u>\$</u>	20,272,661	\$	23,133,679
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable and accrued expenses	\$	1,147,840	\$	773,522
Payroll related liabilities		277,660		1,273,303
Deferred revenue		_		128,708
Capital lease obligations		644,050		898,861
Total current liabilities		2,069,550		3,074,394
Long term liabilities				
Convertible notes payable		6,000,000		6,000,000
Other long term liabilities		568,000		458,000
Capital lease obligations, net of current portion	_	233,826		877,877
Total liabilities	_	8,871,376		10,410,271
Commitments and contingincies (Note 12)				
Stockholders' equity:				
Preferred stock \$.001 par value, 10,000,000 shares authorized,				
none issued and outstanding		_		_
Common stock, \$.001 par value, 80,000,000 shares authorized,				
51,687,046 and 40,123,127 shares issued and outstanding, respectively		51,688		40,124
Additional paid-in capital		113,604,968		97,924,314
Accumulated other comprehensive loss		(10,188)		(163)
Deferred compensation		` _		(19,332)
Accumulated deficit	_	(102,245,183)		(85,221,535)
Total stockholders' equity		11,401,285		12,723,408
Total liabilities and stockholders' equity	\$	20,272,661	\$	23,133,679

	_	2004		the Year Ended December 31, 2003		2002
Revenue						
Product sales and royalties	\$	9,519	\$	6,206	\$	63,417
Research and development fees		349,850		104,537		84,611
Total revenue		359,369		110,743		148,028
Costs and expenses						
Cost of products sold		_		_		27,030
Research and development		10,684,477		8,439,340		21,615,787
General and administrative		6,979,730		5,900,569		6,065,347
Total costs and expenses		17,664,207		14,339,909		27,708,164
Loss from operations		(17,304,838)		(14,229,166)		(27,560,136)
Other income (expense)						
Other income (expense)		82,271		(152,867)		(81,008)
Interest income		85,000		75,574		141,266
Interest expense		(425,128)		(3,159,338)		(384,286)
Total other expense		(257,857)		(3,236,631)		(324,028)
Loss before benefit from income taxes		(17,562,695)		(17,465,797)		(27,884,164)
Benefit from income taxes		539,047		232,231		242,645
Net loss		(17,023,648)		(17,233,566)		(27,641,519)
Deemed dividend to preferred shareholders						
from beneficial conversion feature		_		(2,942,656)		_
Preferred dividend		<u> </u>	_	(175,188)		_
Net loss applicable to common stock		(17,023,648)		(20,351,410)		(27,641,519)
Other comprehensive loss						
Foreign currency translation adjustments		(13,671)		3,348		(223)
Unrealized gain (loss) on marketable securities		<u> </u>	_	(3,646)	_	2,562
Comprehensive loss	\$	(17,037,319)	\$	(17,233,864)	\$	(27,639,180)
Basic and diluted loss per share	\$	(.39)	\$	(.60)	\$	(1.03)
Weighted average common shares outstanding						
used for basic and diluted loss per share		43,603,546		33,649,774		26,937,200

								Accumula comprehen (los	sive income	
	Common Stock (Shares)	Common Stock (Amount)	Preferred Stock (Shares)	Preferred Stock (Amount)	Additional Paid-In Capital	Accumulated Deficit	Deferred Compensation	Foreign Currency	Unrealized loss on	Total Stockholders' Equity
Balance at January 1, 2002	25,541,934	25,542	_	\$ 0	\$ 64,538,838	\$ (40,346,450)	\$ (6,704)	\$ 358	\$ (103,719)	\$ 24,107,865
Issuance of common stock from private placement, net of commission paid	2,666,670	2,667			5,729,204	_	_	_	_	5,731,871
Issuance of common stock upon exercise of stock options Issuance of compensatory options	53,000	53			18,447	_	_	_	_	18,500
and warrants to consultants Issuance of common stock to Board	_	_			71,840	_	_	_	_	71,840
of Directors	32,115	32			56,468	_	(15,000)			41,500
Issuance of common stock to employees as bonus Issuance of warrants as debt issuance	_	_			104,392	_	(78,294)	_	_	26,098
cost Discount on convertible note payable	_ _				66,861 795,701	_ _				66,861 795,701
Amortization of deferred compensation expense Unrealized loss from available-for-	_	_			_	_	2,436	_	_	2,436
sale securities Cumulative translation adjustment	_ _	_ _			_ _	=	_ _	(223)	2,562	2,562 (223)
Net loss						(27,641,519)	<u> </u>			(27,641,519)
Balance at December 31, 2002	28,293,719	28,294	_	_	71,381,751	(67,987,969)	(97,562)	135	(101,157)	3,223,492
Issuance of common stock from private placement, net of commission paid	3,126,655	3,127	_	_	10,246,854	_	_	_	_	10,249,981
Issuance of common stock upon exercise of options and										
warrants Issuance of compensatory options and warrants to	750,795	751	_	_	916,011	_	_	_	_	916,762
consultants Issuance of common stock to Board			_	_	253,402	_	_	_	_	253,402
of Directors	15,268	15		_	54,988	_	(35,000)			20,003
Stock based compensation to employees	186,938	187	_	_	15,832	_	78,294	_	_	94,313
Issuance of preferred stock with detachable warrants and beneficial conversion feature,										
net of issue costs Issuance of common stock upon	_	_	800	1	7,396,623	_	_	_	_	7,397,424
of preferred stock, including dividends paid in stock	5,170,907	5,171	(800)	(1	) (5,171)	_	_	_	_	(801)
Discount on convertible notes, including beneficial										
conversion features and fair value of detachable warrants	_	_	_	_	2,141,417	_	_	_	_	2,141,417
Issuance of common stock upon conversion										
of convertible notes, including interest paid in stock Stock surrendered by officer and	2,603,160	2,603	_	_	5,641,970	_	_	_	_	5,644,573
retired in payment of loan	(24,315)	(24)	. —	_	(119,363)	_	_	_	_	(119,387)
Realized loss on sale of securities Amortization of deferred	_	_	_	_	_	_	_	_	101,157	101,157
compensation expense Unrealized loss from available-for-	_			_	_		34,936	_	(2.646)	34,936
sale securities Cumulative translation adjustment Net loss						(17,233,566)		3,348	(3,646)	(3,646) 3,348 (17,233,566)
Balance at December 31, 2003	40,123,127	40,124			97,924,314	(\$85,221,535)	(19,332)	\$ 3,483	(\$3,646)	12,723,408
Issuance of common stock from private placement, net of										
commission paid Issuance of common stock	11,011,978	11,012	_	_	14,194,674	_	_	_	_	14,205,686

upon exercise of stock options and										
warrants	200,482	200	_	_	187,472	_	_	_	_	187,672
Issuance of compensatory options										
and warrants to										
consultants	_	_	_	_	330,215	_	_	_	_	330,215
Issuance of common stock in										
payment of interest on										
convertible notes	130,673	131	_	_	243,202		_	_	_	243,333
Issuance of common stock to										
employees as bonus	101,850	102	_	_	544,427	_	_	_	_	544,529
Issuance of common stock in										
settlement of lawsuit	118,936	119	_	_	180,664	_	_	_	_	180,783
Amortization of deferred										
compensation expense	_	_	_	_	_	_	19,332	_	_	19,332
Realized loss on sale of securities	_	_	_	_	_		_		3,646	3,646
Cumulative translation adjustment	_	_	_	_	_	_	_	(13,671)	_	(13,671)
Net loss	_	_	_	_	_	(17,023,648)	_	_	_	(17,023,648)
Balance at December 31, 2004	51,687,046	51,688	— \$	0 \$	113,604,968	\$ (102,245,183) \$	0 \$	(10,188) \$	0 :	\$ 11,401,285

The accompanying notes are an integral part of these consolidated financial statements.  $$^{24}$$ 

# For the Year Ended December 31,

				December 31,			
		2004		2003		2002	
Cash flows from operating activities							
Net loss	\$	(17,023,648)	\$	(17,233,566)	\$	(27,641,519)	
Adjustments to reconcile net loss to net cash							
used in operating activities							
Depreciation and amortization		996,043		1,250,667		882,854	
Non-cash interest, amortization of debt discount and							
deferred financing costs		254,682		3,166,072		183,582	
Non-cash compensation expense		1,074,859		408,636		141,874	
Non-cash insurance expense (income)		_		3,501		(2,155)	
Net loss on sale of marketable securities		8,421		94,824		142,291	
Loss on disposal of property and equipment		18,982		114,542		_	
Decrease (increase) in prepaid expense and other assets		82,912		(1,109,109)		381,449	
(Decrease) increase in deferred revenue		(128,708)		128,708		_	
(Decrease) increase in payroll related liabilities		(995,643)		918,311		354,992	
Increase in other long term liabilities		110,000		108,000		350,000	
Increase (decrease) in accounts payable and accrued expenses		374,318		(3,395,927)		1,974,719	
Net cash used in operating activities		(15,227,782)		(15,545,341)		(23,231,913)	
Cash flows from investing activities			-				
Capital expenditures		(145,809)		(441,297)		(4,698,900)	
Issuance of note receivable				_		(309,575)	
Proceeds from collection of note receivable		48,341		198,348		62,886	
Purchases of short term investments and marketable securities		(1,897,584)		(504,850)		(3,610,747)	
Proceeds from sale/redemption of certificates of deposits,		_		(0.0.1,00.0)		(5,011,117)	
marketable securities and short term investments		1,010,079		545,200		8,763,279	
Net cash provided by (used in) investing activities		(984,973)	_	(202,599)		206,943	
Cash flows from financing activities		(501,575)	_	(202,33)		200,515	
Issuance of common stock, net of offering costs		14,205,686		10,869,392		5,744,371	
Proceeds from exercise of stock options		187,672		297,349		6,000	
Issuance of preferred stock, net of offering costs		167,072		7,396,623		0,000	
Issuance of notes payable, net of debt issue costs		_		7,510,445		4,696,399	
Repayment of notes payable		_		(950,000)		4,090,399	
Proceeds from capital lease financing for equipment		_				1 111 427	
Principal payments on capital lease obligations		(909 961)		738,731		1,111,427	
Net cash provided by financing activities		(898,861)	_	(673,883)		(411,658)	
		13,494,497	-	25,188,657	_	11,146,539	
Effect of foreign exchange on cash		(13,671)	_	3,348	_	(223)	
Net (decrease) increase in cash and cash equivalents		(2,731,929)		9,444,065		(11,878,654)	
Cash and cash equivalents							
Beginning of year		10,479,214	_	1,035,149		12,913,803	
End of year	<u>\$</u>	7,747,285	\$	10,479,214	\$	1,035,149	
0.1	ø.	120.062	e.	1.42.950	Ф	106.055	
Cash paid for interest	\$	120,962	\$	142,850	\$	196,955	
Supplemental disclosure of non-cash investing and financing activities:							
Property and equipment acquired through capital lease obligations	\$	_	\$	738,731	\$	1,111,427	
Conversion of debt to common stock		_		5,600,000		_	
Payment of interest in common stock		243,333		275,448			
Conversion of preferred stock to common stock		_		2,019,826		_	
Preferred stock dividend paid in common stock		_		175,188			
Amortization of debt discount		_		2,811,110		126,006	
Deemed dividend to preferred shareholders		_		2,942,656			
•							

Deemed dividend to warrant holders	_	120,717	_
Repayment of officer loan in stock	_	119,387	_

The accompanying notes are an integral part of these consolidated financial statements. \$25\$

# 1. Organization and Basis of Presentation

The Company was incorporated in Nevada in 1987. In January 1994, the Company began research and development of a device for the treatment of herpes simplex. The Company, since 1995, has conducted research and development both domestically and abroad on proprietary pharmaceutical products, with the goal of growing through acquisition and development of pharmaceutical products and technology.

The accompanying consolidated financial statements have been prepared on a basis which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has an accumulated deficit of \$102,245,183 at December 31, 2004 and expects that it will incur additional losses in the future completing the research, development and commercialization of its technologies. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. Management anticipates that it will require additional financing, which it is actively pursuing, to fund operations, including continued research, development and clinical trials of the Company's product candidates. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining financing on terms acceptable to the Company. If the Company is unable to obtain additional financing, operations will need to be discontinued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### 2. Summary of Significant Accounting Principles

Significant accounting principles followed by the Company in preparing its financial statements are as follows:

## Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

#### Reclassifications

Reclassifications of certain amounts for prior years have been recorded to conform to the current year presentation.

## Translation of foreign currencies

The functional currency of the Company's foreign subsidiary located in Hong Kong is the local currency. Assets and liabilities of the Company's foreign subsidiaries are translated to United States dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at average exchange rates prevailing during the reporting period. Translation adjustments are accumulated in a separate component of stockholder's equity. Transaction gains or losses are included in the determination of operating results.

# Cash and cash equivalents

For purposes of the balance sheets and the statements of cash flows, cash equivalents represent all highly liquid investments with an original maturity date of three months or less.

#### Marketable securities and short term investments

Marketable securities consist of high quality corporate and government securities, which have original maturities of more than three months, at the date of purchase, and equity investments in publicly-traded companies. The Company classifies all debt securities and equity securities with readily determinable market value as "available for sale" in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These investments are carried at fair market value with unrealized gains and losses reported as a separate component of stockholders' equity. Gross unrealized losses were none and \$3,646 for 2004 and 2003, respectively. All unrealized losses were less than 12 months in nature. Gross realized gains from the sales of securities classified as available for sale were none, \$17,016, and \$143,971 and gross realized losses were \$8,421, \$111,840, and \$1,680 for 2004, 2003 and 2002 respectively. For the purpose of determining realized gains and losses, the cost of securities sold was based on specific identification. The Company reviews investments on a quarterly basis for reductions in market value that are other than temporary. When such reductions occur, the cost of the investment is adjusted to its fair value through a charge to other income (expense) in the periods incurred.

#### NexMed, Inc.

#### Notes to Consolidated Financial Statements

A significant amount of our short term investments are comprised of investment grade variable rate debt obligations, which are asset-backed and categorized as available-for-sale. Accordingly, our investments in these securities are recorded at cost, which approximates fair value due to their variable interest rates, which typically reset every 28 days. Despite the long-term nature of their contractual maturities, we have the ability and intent liquidate these securities within one year. As a result of the resetting variable rates, we had no cumulative gross unrealized or realized holding gains or losses from these investments. All income generated from these investments was recorded as interest income.

#### Fair value of financial instruments

The carrying value of cash and cash equivalents, convertible notes payable and accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments.

#### Fixed assets

Property and equipment are stated at cost less accumulated depreciation. Depreciation of equipment and furniture and fixtures is provided on a straight-line basis over the estimated useful lives of the assets, generally three to ten years. Depreciation of buildings is provided on a straight-line basis over the estimated useful life of 31 years. Amortization of leasehold improvements is provided on a straight-line basis over the shorter of their estimated useful life or the lease term. The costs of additions and betterments are capitalized, and repairs and maintenance costs are charged to operations in the periods incurred.

#### Long-lived assets

The Company reviews for the impairment of long-lived assets whenever events or circumstances indicate that the carrying amount of an asset may not be 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 is less than its carrying amount. If such assets are considered impaired, the amount of the impairment loss recognized is measured as the amount by which the carrying value of the asset exceeds the fair value of the asset, fair value being determined based upon discounted cash flows or appraised values, depending on the nature of the asset. No such impairment losses have been recorded by the Company during 2004, 2003 or 2002.

#### Revenue recognition

Revenues from product sales are recognized upon delivery of products to customers, less allowances for estimated returns and discounts. Royalty revenue is recognized upon the sale of the related products, provided the royalty amounts are fixed or determinable and the amounts are considered collectible.

Revenues earned under research and development contracts are recognized in accordance with the cost-to-cost method outlined in Staff Accounting Bulletin No. 101, as amended, whereby the extent of progress toward completion is measured on the cost-to-cost basis; however, revenue recognized at any point will not exceed the cash received. When the current estimates of total contract revenue and contract cost indicate a loss, a provision for the entire loss on the contract is made in the period which it becomes probable. All costs related to these agreements are expensed as incurred and classified within "Research and development" expenses in the Consolidated Statement of Operations and Comprehensive Income.

#### Research and development

Research and development costs are expensed as incurred and include the cost of salaries, building costs, utilities, allocation of indirect costs, and expenses to third parties who conduct research and development, pursuant to development and consulting agreements, on behalf of the Company.

#### Income taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax bases of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized.

#### Loss per common share

Basic earnings per share is computed by dividing income available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period. The computation of diluted earnings per share does not assume conversion, exercise or contingent exercise of securities that would have an antidilutive effect on per share amounts.

At December 31, 2004, 2003 and 2002, outstanding options to purchase 5,215,081, 5,414,617, and 4,750,755 shares of common stock, respectively, with exercise prices ranging from \$.55 to \$16.25 have been excluded from the computation of diluted loss per share as they are antidilutive. Outstanding warrants to purchase 11,436,691, 7,272,261, and 2,044,908 shares of common stock, respectively, with exercise prices ranging from \$1.00 to \$4.04 have also been excluded from the computation of diluted loss per share as they are antidilutive. Promissory notes convertible into 1,200,000 and 923,077 shares of common stock (see Note 5) in 2004 and 2003 respectively have also been excluded from the computation of diluted loss per share, as they are antidilutive.

#### Accounting for stock based compensation

As provided by SFAS 123, Accounting for Stock-Based Compensation ("SFAS 123") as amended by SFAS 148, the Company has elected to continue to account for its stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Accordingly, compensation expense has been recognized to the extent of employee or director services rendered based on the intrinsic value of compensatory options or shares granted under the plans. The Company has adopted the disclosure provisions required by SFAS 123.

Had the Company's stock-based compensation been determined by the fair-value based method of SFAS 123, "Accounting for Stock-Based Compensation," the Company's net loss and loss per share would have been as follows:

	For the year ended				
	 2004		2003		2002
Net loss applicable to common stock, as reported	\$ (17,023,648)	\$	(20,351,410)	\$	(27,641,519)
Add: Stock-based compensation expense included					
in reported net loss	355,800		408,636		141,874
Deduct: Total stock-based compensation expense determined					
under fair-value based method for all awards	(1,672,545)		(2,211,685)		(2,591,717)
Proforma net loss applicable to common stock	\$ (18,340,393)	\$	(22,154,459)	\$	(30,091,362)
Basic and diluted loss per share:					
As reported	\$ (0.39)	\$	(0.60)	\$	(1.03)
Proforma	\$ (0.42)	\$	(0.66)	\$	(1.12)

Additional disclosures required under SFAS 123 are presented in Note 7.

#### Concentration of credit risk

From time to time, the Company maintains cash in bank accounts that exceed the FDIC insured limits. The Company has not experienced any losses on its cash accounts.

## Comprehensive loss

We have recorded comprehensive loss in accordance with Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income" ("SFAS 130"), which requires the presentation of the components of comprehensive loss in the Company's financial statements. Comprehensive loss is defined as the change in the Company's equity during a financial reporting period from transactions and other circumstances from non-owner sources (including cumulative translation adjustments and unrealized gains/losses on available for sale securities). Accumulated other comprehensive (loss) income included in the Company's balance sheet is comprised of translation adjustments from the Company's foreign subsidiaries and unrealized gains and losses on investment in marketable securities.

## Accounting estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's most significant estimates relate to the valuation of its long-lived assets, estimated cost to complete under its research contracts, and valuation allowances for its deferred tax benefit. Actual results may differ from those estimates.

# Recent accounting pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No.123(R), Share-Based Payment. SFAS 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS 123(R), companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees. Instead, companies will be required to account for such transactions using a fair-value method and to recognize compensation expense over the period during which an employee is required to provide services in exchange for the award. The provisions of SFAS 123(R) are effective for periods beginning after June 15, 2005, and apply to all awards that vest after the required effective date and to awards that are granted, modified, repurchased, or cancelled after that date. For an approximate impact on 2005 results please refer to the pro forma information above in the Accounting for Stock Based Compensation Note.

#### NexMed, Inc.

#### Notes to Consolidated Financial Statements

In March 2004, the Emerging Issues Task Force issued EITF 03-6, "Participating Securities and the Two-Class Method under FASB Statement No. 128". This statement provides additional guidance on the calculation and disclosure requirements for earnings per share. The FASB concluded in EITF 03-6 that companies with multiple classes of common stock or participating securities, as defined by SFAS No. 128, should calculate and disclose earnings per share based on the two-class method. The adoption of this statement does not have an impact to the Company's financial statement presentation as the Company is currently in a loss position.

In January 2003, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 46 "Consolidation of Variable Interest Entities" ("FIN 46"). Variable Interest Entities ("VIEs") are entities where control is achieved through means other than voting rights. FIN 46 provides guidance on the identification of and financial reporting for VIEs. A VIE is required to be consolidated if the company is subject to the majority of the risk of loss from the VIE's activities or is entitled to receive a majority of the entity's residual returns, or both. Certain provisions of FIN 46 were effective during 2003; however generally FIN 46 must be applied to the first reporting period ending after March 15, 2004. The adoption of this Interpretation does not have any impact on the Company's consolidated financial statements.

## 3. Research and Development Agreements

In November 2003, the Company entered into an agreement with a Japanese pharmaceutical company whereby NexMed would provide contract development services for an innovative topical treatment for a form of herpes. The Company received \$100,000 as a signing payment in 2003, approximately \$87,000 of which the Company recognized as revenue in 2004 and approximately \$13,000 of which it recognized as revenue in 2003. In 2004, the Company recognized revenue of approximately \$217,000 and incurred expenses of approximately \$116,000 related to this agreement. The \$217,000 of revenue consisted of the \$87,000 deferred from 2003 and \$130,000 in milestone payments received in 2004. In September of 2004, the Company completed all development work for this project and will recognize no further revenue.

In November 2003, the Company entered into an R&D agreement with a Japanese pharmaceutical company to develop a new local anesthetics gel designed for pain relief associated with dental procedures, superficial skin surgery and skin graft harvesting, and needle insertions. The Company recognized revenue of approximately \$41,000 in 2004 and \$5,000 in 2003 related to this project. In 2004, the Company incurred expenses of approximately \$32,000, completed all development work and will recognize no further revenue related to this project.

In October 2003, the Company entered into an R&D agreement with a Japanese pharmaceutical company to develop a tape/patch treatment for chronic pain. The Company recognized revenue of approximately \$21,000 in 2003. The second milestone payment of approximately \$69,000 was received and recognized as research and development fee revenue in 2004. In 2004, the Company incurred expenses of approximately \$40,500 related to this agreement and completed the first phase of development. Upon completion of the first phase of development, the development partner decided to suspend all remaining development work on this project due to new regulatory developments in Japan. As such, there will be no additional revenue from the Japanese pharmaceutical company should the Company continue to develop this product further.

In August 2003, the Company entered into an R&D agreement with a Japanese pharmaceutical company to develop NM 20138, a new once-a-day patch treatment for bronchial asthma, which incorporates an off-patent anti-asthmatic drug compound and the NexACT® technology. The Company recognized revenue related to this project of approximately \$21,000 in 2003. The second milestone payment of approximately \$23,000 was received and recognized as research and development fee revenue in 2004. In 2004, the Company incurred expenses of approximately \$62,000 related to this agreement and completed the first phase of development. Upon completion of the first phase of development, the partner elected not to take the project to the next stage of development due to proprietary reasons. As such, there will be no additional revenue from the Japanese pharmaceutical company should the Company continue to develop this product further. The Company negotiated and received a one-time payment of \$90,538 upon cancellation of this agreement, which amount is recorded in other income (expense) in the Company's Consolidated Statement of Operations.

#### 4. Fixed Assets

Fixed assets at December 31, 2004 and 2003 were comprised of the following:

	2004	2003
Land	363,909	363,909
Building	7,457,791	7,210,118
Machinery and equipment	993,385	1,191,707
Capital lease - Equipment	2,861,335	2,881,220
Computer software	565,158	565,158
Furniture and fixtures	342,724	343,971
Leasehold improvements	637,907	637,907
	13,222,209	13,193,990
Less: accumulated depreciation	(3,507,759)	(2,610,257)
	\$ 9,714,450	\$ 10,583,733

Depreciation and amortization expense was \$996,043, \$1,250,667, and \$882,855 for 2004, 2003 and 2002 respectively, of which \$410,833, \$424,778 and \$268,716 related to capital leases for the respective years. Accumulated amortization of assets under capital leases was \$1,207,027 and \$796,144 at December 31, 2004 and 2003, respectively.

# 5. Convertible Notes Payable

On December 12, 2003, the Company issued convertible notes (the "Notes") in an aggregate principal amount of \$6 million. The Notes are payable on May 31, 2007 and are collateralized by the Company's manufacturing facility in East Windsor, New Jersey which has a carrying value of approximately \$6.9 million. The Notes were initially convertible into shares of the Company's common stock at a conversion price initially equal to \$6.50 per share (923,077 shares). Pursuant to the terms of the Notes, the conversion price was adjusted on June 14, 2004 to the volume weighted average price of the Company's stock over the six-month period ending on such date Since the volume weighted average price of the Company's stock during this period was below \$5.00, the conversion price was adjusted to \$5.00 (1,200,000 shares). Interest accretes on the Notes on a semi-annual basis at a rate of 5% per annum, and the Company may pay such amounts in cash or by effecting the automatic conversion of such amount into the Company's common stock at a 5% premium to the then average market prices.

In April and October 2004, respectively, the Company issued 32,913 shares and 97,760 shares of its common stock as payment of an aggregate of \$243,333 in interest on the Notes.

For the years ended December 31, 2004 and 2003, the Company recorded amortization of the debt discount of none and \$2,811,110, respectively and amortization of debt issuance costs of \$11,349 and \$82,807, respectively.

## 6. Line of Credit

In February 2001, the Company entered into a financial arrangement with GE Capital Corporation for a line of credit, which provided for the financing of up to \$5 million of equipment (i) for its new East Windsor, NJ manufacturing facility and (ii) for its expanded corporate and laboratory facilities in Robbinsville, NJ. Equipment financed through this facility was in the form of a 42-month capital lease. As of December 31, 2002, the Company had financed \$1,113,459 of equipment purchases under the GE credit line. The \$5 million credit line expired in March 2002, and as of December 31, 2004, there was an outstanding balance due GE of \$57,832 under this facility. This balance is payable in monthly installments through various dates in 2005.

In January 2002, GE approved a new credit line, which provided for the financing of up to \$3 million of equipment and expired on December 31, 2002. During 2002, the Company accessed \$1,111,427 of the credit line. As of December 31, 2004, there was an outstanding balance due GE of \$375,571 under the January 2002 facility. Balances due are payable in 42 monthly installments from date of take-down.

In July 2003, GE approved a new credit line, which expired on July 2004 and provided for the financing of up to \$1.85 million of equipment. During 2003 and 2004, the Company accessed \$738,731 of this credit line. As of December 31, 2004, there was an outstanding balance due GE of \$444,473 under the July 2003 facility, payable in 36 monthly installments from the date of take-down.

#### 7. Stock Options

During October 1996 the Company adopted a Non-Qualified Stock Option Plan ("Stock Option Plan") and reserved 100,000 shares of common stock for issuance pursuant to the Plan. During December 1996, the Company also adopted The NexMed, Inc. Stock Option and Long-Term Incentive Compensation Plan ("the Incentive Plan") and The NexMed, Inc. Recognition and Retention Stock Incentive Plan ("the Recognition Plan"). A total of 2,000,000 shares were set aside for these two plans. In May 2000, the Stockholders' approved an increase in the number of shares reserved for the Incentive Plan and Recognition Plan to a total of 7,500,000. Options granted under the Company's plans generally vest over a period of one to five years, with exercise prices of currently outstanding options ranging between \$0.55 to \$16.25. The maximum term under these plans is 10 years.

A summary of stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2001	3,834,575	\$ 3.72
Granted	1,555,573	1.35
Exercised	(53,000)	0.35
Cancelled	(586,393)	4.04
Outstanding at December 31, 2002	4,750,755	\$ 2.92
Granted	1,110,350	2.80
Exercised	(326,074)	0.88
Cancelled	(120,414)	6.37
Outstanding at December 31, 2003	5,414,617	\$ 2.94
Granted	731,150	2.41
Exercised	(192,986)	0.90
Cancelled	(737,700)	3.22
Outstanding at December 31, 2004	5,215,081	\$ 2.91
Exercisable at December 31, 2004	3,975,628	\$ 2.93
Exercisable at December 31, 2003	4,269,617	\$ 2.92
Exercisable at December 31, 2002	3,162,900	\$ 3.46
Options available for grant at December 31, 2004	1,167,973	
	13	

The following table summarizes information about options outstanding at December 31, 2004:

Options Outstanding					Opt	ions Exercisable
		Weighted Average				
Range of	Number	Remaining		Weighted Average	Number	Weighted Average
<b>Exercise Prices</b>	Outstanding	Contractual Life		Exercise Price	Exercisable	Exercise Price
\$ .55 - 1.85	1,458,531	7.74 years	\$	1.12	944,378	\$ 0.88
2.00 - 3.99	2,030,650	3.50 years		2.52	1,561,100	2.31
4.00 - 5.50	1,614,000	5.86 years		4.21	1,358,250	4.09
7.00 - 8.00	15,000	5.40 years		8.00	15,000	8.00
12.00 - 16.25	96,900	5.83 years		15.79	96,900	15.79
	5,215,081		\$	2.91	3,975,628	\$ 2.93

The weighted average grant date fair value of options granted during 2004, 2003 and 2002 was \$2.46, \$2.60 and \$1.23, respectively.

The fair value of each option and warrant (note 10) is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used in the model:

	2004	2003	2002
Dividend yield	0.00%	0.00%	0.00%
Risk-free yields	1.35% - 4.58%	1.35% - 4.58%	1.35% - 3.00%
Expected volatility	100%	100%	100%
Expected option life	1 - 10 years	1 - 10 years	1 - 10 years

#### 8. Common Stock

Pursuant to a Common Stock and Warrant Purchase Agreement dated December 17, 2004, the Company closed a private placement of its securities and raised over \$7 million in gross proceeds. The Company sold 5,495,310 shares of its common stock at \$1.28 per share. The investors also received five-year warrants to purchase 2,198,126 shares of common stock, exercisable beginning six months after closing at a price of \$1.47 per share. In addition, the investors also received one-year warrants to purchase 549,536 shares of common stock, exercisable at a price of \$2.00 per share.

In June 2004, the Company raised over \$8.27 million in gross proceeds from a private placement of its securities. The Company sold 5,516,668 shares of its common stock at \$1.50 per share. The investors also received five-year warrants to purchase 1,930,834 shares of common stock, exercisable beginning six months after closing, at an exercise price of \$2.00 per share.

#### NexMed, Inc.

#### Notes to Consolidated Financial Statements

On July 2, 2003, the Company closed a private placement of its common stock at \$3.60 per share and issued a total of 2,916,669 shares and 1,020,832 four-year warrants to purchase shares of the Company's common stock at \$5.04 per share. One third of the warrants are callable by the company if the market price of the Company's common stock closes above \$10.00 for seven consecutive trading days. The Company received \$10.5 million in gross proceeds.

On March 21, 2003, the Company closed a private placement of its common stock at \$1.50 per share. Pursuant to the agreement, the Company issued a total of 210,000 shares and 157,500 three-year warrants to purchase the Company's common stock at \$2.00 per share and received \$315,000 in gross proceeds.

#### 9. Stockholder Rights Plan

On April 3, 2000, the Company declared a dividend distribution of one preferred share purchase right (the "Right") for each outstanding share of the Company's common stock to shareholders of record at the close of business on April 21, 2000. One Right will also be distributed for each share of Common Stock issued after April 21, 2000, until the Distribution Date described in the next paragraph. Each Right entitles the registered holder to purchase from the Company a unit consisting of one one-hundredths of a share (a "Unit") of Series A Junior Participating Preferred Stock, \$.001 par value per share (the "Preferred Stock"), at a Purchase Price of \$100.00 per Unit, subject to adjustment. 1,000,000 shares of the Company's preferred stock have been set-aside for the Rights Plan.

Initially, the Rights will be attached to all Common Stock certificates representing shares then outstanding, and no separate Rights Certificates will be distributed. The Rights will separate from the Common Stock and a Distribution Date will occur upon the earlier of (i) ten (10) business days following a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the outstanding shares of Common Stock (the "Stock Acquisition Date"), or (ii) ten (10) business days following the public announcement of a tender offer or exchange offer that would, if consummated, result in a person or group beneficially owning 15% or more of such outstanding shares of Common Stock, subject to certain limitations.

Under the terms of the Rights Agreement, Dr. Y. Joseph Mo, who beneficially owned approximately 12.12% of the outstanding shares of the Company's Common Stock as of April 2000, will be permitted to continue to own such shares and to increase such ownership to up to 25% of the outstanding shares of Common Stock, without becoming an Acquiring Person and triggering a Distribution Date.

#### 10. Warrants

A summary of warrant activity is as follows:

	Common Shares Issuable upon Exercise	Weighted Average Exercise Price
Outstanding at January 1, 2002	2,206,549	\$ 11.59
Issued	1,183,850	3.27
Redeemed	(1,345,491)	14.31
Outstanding at December 31, 2002	2,044,908	5.03
Issued	5,959,990	2.10
Redeemed	(424,811)	3.96
Cancelled	(307,826)	14.37
Outstanding at December 31, 2003	7,272,261	2.32
Issued	5,128,496	1.86
Redeemed	(7,500)	1.94
Cancelled	(956,566)	3.67
Outstanding at December 31, 2004	11,436,691	\$ 1.91

#### 11. Income Taxes

The Company has incurred losses since inception, which have generated net operating loss carryforwards of approximately \$65.1 million for federal and state income tax purposes. These carryforwards are available to offset future taxable income and expire beginning in 2014 through 2024 for federal income tax purposes. In addition, the Company has general business and research and development tax credit carryforwards of approximately \$1.8 million. Internal Revenue Code Section 382 places a limitation on the utilization of Federal net operating loss carryforwards when an ownership change, as defined by tax law, occurs. Generally, an ownership change, as defined, occurs when a greater than 50 percent change in ownership takes place during any three-year period. The actual utilization of net operating loss carryforwards generated prior to such changes in ownership will be limited, in any one year, to a percentage of fair market value of the Company at the time of the ownership change. Such a change may have already resulted from the additional equity financing obtained by the Company since its formation.

In 2002, 2003 and 2004, the Company was approved by the State of New Jersey to sell a portion of its state tax credits pursuant to the Technology Tax Certificate Transfer Program. The Company has approximately \$4.6 million in NJ tax credits, and was approved to sell \$605,671 in 2004, \$261,000 in 2003 and \$279,000 in 2002. The Company received net proceeds of \$539,047, \$232,231, and \$242,645 in 2004, 2003 and 2002, respectively, as a result of the sale of the tax credits.

The net operating loss carryforwards and tax credit carryforwards resulted in a noncurrent deferred tax benefit at December 31, 2004 and 2003 of approximately \$28.5 million and \$23.1 million, respectively. In consideration of the Company's accumulated losses and the uncertainty of its ability to utilize this deferred tax benefit in the future, the Company has recorded a valuation allowance of an equal amount on such date to fully offset the deferred tax benefit amount.

The reconciliation of income taxes computed using the statutory U.S. income tax rate and the provision (benefit) for income taxes for the years ended December 31, 2004, 2003 and 2002 are as follows:

		For the years ended December 31,			
	2004	2003	2002		
Federal statutory tax rate	(35%)	(35%)	(35%)		
State taxes, net of federal benefit	(6%)	(6%)	(6%)		
Valuation allowance	(41%)	(41%)	(41%)		
Sale of state net operating losses	(3.16%)	(1.33%)	(0.87%)		
Provision (benefit) for income taxes	(3.16%)	(1.33%)	(0.87%)		

For the years ended December 31, 2004, 2003 and 2002, the Company's effective tax rate differs from the federal statutory rate principally due to net operating losses and other temporary differences for which no benefit was recorded, state taxes and other permanent differences.

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards.

#### 12. Commitments and Contingencies

The Company is a party to clinical research agreements totaling approximately \$12.8 million. These agreements provide that upon cancellation, the Company will owe 10% of the outstanding contract amount at the time of cancellation. At December 31, 2004, this amounts to approximately \$1,100,000. The Company anticipates that the clinical research in connection with the agreements will be completed in 2006.

The Company is a party to several short-term consulting and research agreements that, generally, can be cancelled at will by either party.

A lawsuit was filed with the Superior court of New Jersey on April 1, 2003 by one former employee against the Company for an unspecified bonus amount that he believes he should have received upon completion of the construction of the Company's East Windsor manufacturing facility. The Company has engaged counsel to defend its position and intends to defend itself vigorously against the above-mentioned claim and believes it has valid defenses; however, the case is still in the preliminary stages and the likely outcomes cannot be predicted, nor can a reasonable estimate of the amount of loss, if any, be made.

The Company leases office space and research facilities under operating lease agreements expiring through 2006. The Company also leases equipment from GE Capital under capital leases expiring through 2006 (Note 7). Future minimum payments under noncancellable operating and capital leases with initial or remaining terms of one year or more, consist of the following at December 31, 2004:

	Operating	Capital
2005	469,378	690,816
2006	100,823	241,099
2007	2,100	_
Total minimum lease payments	\$ 572,301	931,915
Less: amount representing interest		(54,039)
Present value of future minimum lease payments		877,876
Less: current portion		(644,050)
Capital lease obligations, net of current portion		\$ 233,826

The Company also leases office space under short-term lease agreements. Total rent expense was \$484,053, \$460,643, and \$452,052 in 2004, 2003, and 2002 respectively.

On February 27, 2002, the Company entered in to an employment agreement with Y. Joseph Mo, Ph.D., that has a constant term of five years, and pursuant to which Dr. Mo will serve as the Company's Chief Executive Officer and President. During his employment with the Company, Dr. Mo will receive an annual base salary of at least \$250,000 (to be raised to \$350,000 after the Company sustains gross revenues of \$10 million for two consecutive fiscal quarters), subject to annual cost of living increases. Under the employment agreement, Dr. Mo is entitled to deferred compensation in an annual amount equal to one sixth of the sum of his base salary and bonus for the 36 calendar months preceding the date on which the deferred compensation payments commence subject to certain limitations, including annual vesting through January 1, 2007, as set forth in the employment agreement. The deferred compensation will be payable monthly for 180 months commencing on termination of employment. As of December 31, 2004 and 2003, the Company has accrued approximately \$568,000 and \$458,000 respectively, which is included in other long-term liabilities, based upon the estimated present value of the vested portion of the obligation.

## 13. Segment and Geographic Information

The Company is active in one business segment: designing, developing, manufacturing and marketing pharmaceutical products. The Company maintains development and business development operations in the United States and Hong Kong.

Geographic information as of December 31, 2004, 2003 and 2002 are as follows:

For the	vears	ended	Decemb	er 31.

			2004		2003	2002
Net revenues						
United States		\$	216,891	\$	12,718	\$ _
Hong Kong			142,478		98,025	 148,028
		\$	359,369	\$	110,743	\$ 148,028
				D	ecember 31,	
			2004		2003	 2002
Long-lived assets						
United States		\$	9,714,450	\$	10,583,733	\$ 11,507,564
Hong Kong			<u> </u>		<u> </u>	<u> </u>
		\$	9,714,450	\$	10,583,733	\$ 11,507,564
	39					

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH AUDITORS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### ITEM 9A. CONTROLS AND PROCEDURES

#### Disclosure Controls and Procedures and Changes in Internal Control Over Financial Reporting.

In accordance with Exchange Act Rules 13a-15 and 15d-15, the Company's management carried out an evaluation with participation of the Company's Chief Executive Officer and Chief Financial Officer, its principal executive officer and principal financial officer, respectively, of the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded as of December 31, 2004 that the Company's disclosure control and procedures are effective. There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation by the Chief Executive Officer and Chief Financial Officer that occurred during the Company's fourth quarter that have materially affected or are reasonably likely to materially affect the Company's internal control over financial reporting.

#### Management's Report on Internal Control Over Financial Reporting.

Our Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under such framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

#### ITEM 9B. OTHER INFORMATION.

None.

#### PART III.

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Other than as set forth below, information called for by Item 10 is set forth under the heading "Election of Directors" and "Committees of the Board" in our 2005 Proxy Statement, which is incorporated herein by reference, and "Executive Officers of the Registrant" of Part I of this Report.

The Company has adopted a code of ethics that applies to its Chief Executive Officer, Chief Financial Officer, and to all of its other officers, directors and employees. The code of ethics is available at the Corporate Governance section of the Investor's Info. page on the Company's website at <a href="http://www.nexmed.com">http://www.nexmed.com</a>. The Company intends to disclose future amendments to, or waivers from, certain provisions of its code of ethics, if any, on the above website within four business days following the date of such amendment or waiver.

#### ITEM 11. EXECUTIVE COMPENSATION.

Information called for by Item 11 is set forth under the heading "Executive Compensation" in our 2005 Proxy Statement, which is incorporated herein by reference.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Other than as set forth below, information called for by Item 12 is set forth under the heading "Security Ownership of Certain Beneficial Owners and Management" in our 2005 Proxy Statement, which is incorporated herein by reference.

#### **EQUITY COMPENSATION PLAN INFORMATION**

The following table gives information as of December 31, 2004, about shares of our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans (together, the "Equity Plans"):

	(a)	(b)	(c)
Plan category	Number of securities to be issue upon exercise of outstanding options, warrants and rights	0 0 1	e Number of securities remaining available for future s issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	5,215,081 (1)	\$2.91	1,167,973 (2)
Equity compensation plans not approved by security holders			
Total	5,215,081		1,167,973

<sup>(1)</sup> Consists of options outstanding at December 31, 2004 under The NexMed Inc. Stock Option and Long Term Incentive Plan (the "Incentive Plan") and The NexMed Inc. Recognition and Retention Stock Incentive Plan (the "Recognition Plan").

<sup>(2)</sup> Consists of 885,173 and 282,800 shares of common stock that remain available for future issuance, at December 31, 2004, under the Incentive Plan and Recognition Plan, respectively.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Information called for by Item 13 is set forth under the heading "Certain Relationships and Related Transactions" in our 2005 Proxy Statement, which is incorporated herein by reference.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Information called for by item 14 is set forth under the heading "Principal Accountant Fees and Services" in our 2005 Proxy Statement, which is incorporated herein by reference.

#### PART IV.

#### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

## (a) 1. <u>Financial Statements</u>:

The information required by this item is included in Item 8 of Part II of this Form 10-K.

## 2. <u>Financial Statement Schedules</u>

Schedule II - Valuation and Qualifying Accounts.

## NEXMED, INC. SCHEDULE OF VALUATION AND QUALIFYING ACCOUNTS

Description	Balance at Beginning of Year	(	harged to Costs and Expenses	Charged to Other Accounts	Deductions	Balance at End of Year
Year ended December 31, 2004						
Valuation allowance - deferred tax asset	\$ 23,098,077	\$	5,422,293	-	\$	28,520,370
Year ended December 31, 2003						
Valuation allowance - deferred tax asset	\$ 17,901,534	\$	5,196,543		\$	23,098,077
Year ended December 31, 2002						
Valuation allowance - deferred tax asset	\$ 8,699,708	\$	9,201,826	-	\$	17,901,534

	All other schedules have been omitted because the information is not applicable or is presented in the Financial Statements or Notes thereto.
EXHIBITS NO. 3.1	<ol> <li>Exhibits     DESCRIPTION</li> <li>Amended and Restated Articles of Incorporation of the Company (incorporated by reference to Exhibit 2.1 filed with the Company's     Form 10-SB filed with the Securities and Exchange Commission on March 14, 1997).</li> </ol>
3.2	Amended and Restated By-laws of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 14, 2003).
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3.3 Certificate of Amendment to Articles of Incorporation of the Company, dated June 22, 2000 (incorporated herein by reference to Exhibit 3.2 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 31, 2003). Form of Common Stock Certificate (incorporated by reference to Exhibit 3.1 filed with the Company's Form 10-SB filed with the 4.1 Securities and Exchange Commission on March 14, 1997). 4.2 Rights Agreement and form of Rights Certificate (incorporated herein by reference to Exhibit 4 to our Current Report on Form 8-K filed with the Commission on April 10, 2000). 4.3 Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibit 4 to our Current Report on Form 8-K filed with the Commission on April 10, 2000). 4.4 Certificate of Designation of the Company's Series B 8% Cumulative Convertible Preferred Stock (incorporated herein by reference to Exhibit 4.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 14, 2003). Form of Warrant dated April 21, 2003 (incorporated herein by reference to Exhibit 4.2 to the Company's Form 10-Q filed with the 4.5 Securities and Exchange Commission on May 14, 2003). Form of Common Stock Purchase Warrant dated July 2, 2003 (incorporated herein by reference to Exhibit 4.3 to the Company's 4.6 Registration Statement on Form S-3 filed with the Securities and Exchange Commission on July 17, 2003). 4.7 Form of Warrant dated June 18, 2004 (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed with the Securities and Exchange Commission on June 25, 2004). 10.1\* Amended and Restated NexMed, Inc. Stock Option and Long-Term Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 filed with the Company's Form 10-Q filed with the Securities and Exchange Commission on May 15, 2001). 10.2\* The NexMed, Inc. Recognition and Retention Stock Incentive Plan incorporated by reference to Exhibit 99.1 filed with the Company's Form 8-K filed with the Securities and Exchange Commission on May 28, 2004). 10.3\* Form of Agreement dated November 15, 1995 between NexMed, Inc. and each of Y. Joseph Mo, Ph.D., Vivian H. Liu and Gilbert S. Banker, Ph.D, which are collectively commonly referred to by NexMed, Inc. as the Non-Qualified Performance Incentive Program (filed as Exhibit 4.2 to our Registration Statement on Form 8-A filed with the Securities and Exchange Commission on December 22, 1999, including any amendment or report filed for the purpose of updating such information, and incorporated herein by reference). 10.4 License Agreement dated March 22, 1999 between NexMed International Limited and Vergemont International Limited (incorporated by reference to Exhibit 10.7 of the Company's Form 10-KSB filed with the Securities and Exchange Commission on March 16, 2000). 10.5\* The NexMed, Inc. Non-Qualified Stock Option Plan (incorporated by reference to Exhibit 6.6 filed with the Company's Form 10-SB/A filed with the Securities and Exchange Commission on June 5, 1997).

Employment Agreement dated February 26, 2002 by and between NexMed, Inc. and Dr. Y. Joseph Mo (incorporated by reference to 10.6\* Exhibit 10.7 of the Company's Form 10-K filed with the Securities and Exchange Commission on March 29, 2002). 10.7 Letter Agreement dated February 6, 2001, by and among NexMed, Inc. and General Electric Capital Corporation (incorporated by reference to Exhibit 10.8 of the Company's Form 10-K filed with the Securities and Exchange Commission on March 29, 2002). Letter Agreement dated January 2, 2002, by and among NexMed, Inc. and General Electric Capital Corporation (incorporated by 10.8 reference to Exhibit 10.8 of the Company's Form 10-K filed with the Securities and Exchange Commission on March 29, 2002). Registration Rights Agreement between the Company and The Tailwind Fund Ltd. and Solomon Strategic Holdings, Inc. dated June 11, 10.9 2002 (incorporated herein by reference to Exhibit 10.2 to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 14, 2002). 10.10 Mortgage, Security Agreement and Assignment of Leases and Rents by NexMed (U.S.A.), Inc., a wholly owned subsidiary of the Company, in favor of The Tailwind Fund Ltd. and Solomon Strategic Holdings, Inc. dated June 11, 2002 (incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 14, 2002). 10.11 Preferred Stock and Warrant Purchase Agreement, dated as of April 21, 2003, between the Company and the Purchasers identified on Schedule 1 to the Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 14, 2003). 10.12 Investor Rights Agreement, dated as of April 21, 2003, between the Company and the Purchasers identified on Schedule 1 to the Investor Rights Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 14, 2003). Common Stock and Warrant Purchase Agreement, dated as of July 2, 2003, between the Company and the Purchasers identified on 10.13 Schedule 1 to the Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on July 17, 2003). 10.14 Investor Rights Agreement, dated as of July 2, 2003, between the Company and the Purchasers identified on Schedule 1 to the Investor Rights Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on July 17, 2003). 10.15 Letter Agreement dated July 12, 2003, between NexMed, Inc. and General Electric Capital Corporation (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 12, 2003). Employment Agreement dated September 26, 2003 by and between NexMed, Inc. and James L. Yeager (incorporated herein by reference 10.16\* to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 12, 2003). Employment Agreement dated September 26, 2003 by and between NexMed, Inc. and Kenneth F. Anderson (incorporated herein by 10.17\* reference to Exhibit 10.2 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 12, 2003).

10.18*	Employment Agreement dated September 26, 2003 by and between NexMed, Inc. and Vivian H. Liu (incorporated herein by reference to Exhibit 10.3 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 12, 2003).
10.19*	Amendment dated September 26, 2003 to Employment Agreement by and between Dr. Y. Joseph Mo and NexMed, Inc. dated February 26, 2002 (incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 12, 2003).
10.20	Purchase Agreement, dated as of December 12, 2003, between the Company and the Purchasers named therein (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on January 13, 2004).
10.21	Registration Rights Agreement, dated as of December 12, 2003, between the Company and the Purchasers named therein (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on January 13, 2004).
10.22	Form of 5% Convertible Note due May 31, 2007 (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on January 13, 2004).
10.23	First Amendment of Mortgage, Security Agreement and Assignment of Leases and Rents by NexMed (U.S.A.), Inc., in favor of The Tail Wind Fund Ltd. and Solomon Strategic Holdings, Inc., dated as of December 12, 2003 (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on January 13, 2004).
10.24	Subsidiary Guaranty by NexMed (U.S.A.), Inc., a wholly owned subsidiary of the Company, in favor of The Tailwind Fund Ltd. and Solomon Strategic Holdings, Inc. dated December 12, 2003.
10.25	Common Stock and Warrant Purchase Agreement, dated as of June 18, 2004, between NexMed, Inc. and the Purchases set forth on Schedule 1 thereto (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Securities and Exchange Commission on June 25, 2004).
10.26	Investor Rights Agreement, dated as of June 18, 2004, between the Company and the Purchasers identified on Schedule 1 thereto (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Securities and Exchange Commission on June 25, 2004).
10.27	License, Supply and Distribution Agreement between the Company and Schering AG, Germany, dated July 1, 2004 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 9, 2004).
10.28*	Stock Option Grant Agreement between the Company and Leonard A. Oppenheim dated November 1, 2004 (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 9, 2004).
10.29*	Form of Stock Option Grant Agreement between the Company and its Directors.
21	Subsidiaries.
23	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.

31.1	Chief Executive Officer's Certificate, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Chief Financial Officer's Certificate, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Chief Executive Officer's Certificate, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Chief Financial Officer's Certificate, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>\*</sup>Management compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 15(c) of Form 10-K.

## **SIGNATURES**

Pursuant to the requirements of the Section 13 or 15(d) 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.

NEXMED, INC.

Date: March 16, 2005 By: /s/ Y. Joseph Mo

Y. Joseph Mo

Chairman of the Board of Directors, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>SIGNATURE</u>	TITLE	<u>DATE</u>
/s/ Y. Joseph Mo Y. JOSEPH MO	Chairman of the Board of Directors, President and Chief Executive Officer	March 16, 2005
/s/ Vivian H. Liu VIVIAN H. LIU	Vice President, Chief Financial Officer and Secretary	March 16, 2005
/s/ Mark Westgate MARK WESTGATE	Controller and principal accounting officer	March 16, 2005
/s/ Richard J. Berman RICHARD J. BERMAN	Director	March 16, 2005
/s/ Arthur D. Emil ARTHUR D. EMIL	Director	March 16, 2005
/s/ Sami A. Hashim SAMI A. HASHIM	Director	March 16, 2005
/s/ Leonard A. Oppenheim LEONARD A. OPPENHEIM	Director	March 16, 2005
/s/ Martin Wade III MARTIN WADE III	Director	March 16, 2005

## EXHIBIT INDEX

EXHIBITS NO.	DESCRIPTION
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## NEXMED, INC.

## AGREEMENT EVIDENCING THE GRANT OF A NON-QUALIFIED STOCK OPTION UNDER THE NEXMED, INC. RECOGNITION AND RETENTION STOCK INCENTIVE PLAN TO \_\_\_\_\_\_

Agreement (this "Agreement") effective as of November 1, 2004 (the "Grant Date"), between NexMed, Inc., a Nevada corporation (the "Company"), and ("Grantee").
1. <u>Grant of Option.</u> Pursuant to the NexMed, Inc. Recognition and Retention Stock Incentive Plan (the "Plan"), the Company hereby grants to Grantee, as of the Grant Date, a non-qualified stock option (the "Option"), to purchase an aggregate of shares (the "Option Shares") of Common Stock of the Company (the "Common Stock") at a price of \$ per share subject to adjustment and the other terms and conditions set forth herein and in the Plan.
2. <u>Grantee Bound by Plan.</u> Enclosed is a copy of the Plan, which is incorporated herein by reference and made a part hereof. The Plan shall govern all aspects of this Agreement except as otherwise specifically stated herein. Grantee hereby acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. Unless otherwise defined herein, capitalized terms used but not defined herein shall have the meanings ascribed to them in the Plan. The Plan should be carefully examined before any decision is made to exercise this Option.
3. Exercise of Option. (a) Vesting. Subject to the earlier termination of the Option as provided herein and in the Plan, the Option may be exercised, by written notice to the Company at any time and from time to time after the Grant Date, but, except as otherwise provided below, such Option shall not be exercisable for more than the number of Option Shares which are then vested. This Option shall vest in installments as follows:
(i)% of the Stock Option Shares (which represents Stock Option Shares) shall vest immediately; (ii)% of the Stock Option Shares (which represents Stock Option Shares) shall vest on the date of the Annual Meeting of Shareholders.
(b) Early Expiration of Option. (i) Upon the termination of the Grantee's service with the Company (including any subsidiary thereof) for any reason, including death, any portion of the Option granted hereunder that is not vested and exercisable on the date of such termination shall automatically expire and be forfeited as of such date and the vested portion of the Option shall expire in accordance with subsections (ii) and (iii) of Section 3(b), or, in the event of the Grantee's death, Section 5, as applicable;
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(ii) In the event that the Grantee's service with the Company (including any subsidiary thereof) is terminated for Cause, the Grantee shall automatically forfeit his right to exercise any portion of the Option granted hereunder which shall automatically be cancelled effective on the date of such termination.

- (iii) If, however, the Grantee's service is terminated for any reason other than for Cause, any portion of the Option granted hereunder that is vested but has not been exercised as of the date of such termination shall automatically expire, if not exercised, on the ninetieth (90<sup>th</sup>) day following Grantee's termination of service with the Company, provided, however, that if the Grantee's service terminates due to his retirement or permanent disability, the portion of the Option that is vested but has not been exercised as of the date of the Grantee's termination of service due to retirement or permanent disability shall remain exercisable, subject to the terms and conditions of Section 3 (c) of this Agreement, for a period of one year following the date of the Grantee's termination of service with the Company.
- (c) Normal Expiration of Option. This Option shall not be exercisable after the tenth anniversary of the Grant Date. This Option may not be exercised for a fraction of a share of Common Stock. Unvested Options are subject to cancellation as provided in the Plan.
- (d) Accelerated Vesting. All of the Grantee's outstanding but unvested stock options shall vest immediately upon the occurrence of a Change in Control (as defined in Appendix A hereto).
  - 4. Conditions to Exercise. This Option may not be exercised by Grantee unless the following conditions are met:
- (a) Securities Requirements. Legal counsel for the Company must be satisfied at the time of exercise that the issuance of Option Shares upon exercise will be in compliance with the Securities Act of 1933, as amended (the "Securities Act") and applicable United States federal, state, local and foreign laws; and
- (b) Payment of Exercise Price. At the time of exercise of all or any portion of the Option, the Grantee must pay the full purchase price for the Option Shares being purchased hereunder (i) in cash (or by certified check) or (ii) by delivery of shares of Common Stock previously acquired by the Grantee or (iii) through a combination of option (i) and (ii). Details with respect to the methods for exercise, payment and delivery of Option Shares, including requirements for the payment of withholding taxes applicable thereto are as set forth in the Plan.
- 5. <u>Transferability.</u> This Option may not be sold, assigned, transferred, pledged, hypothecated or otherwise disposed of by Grantee, except by will or the laws of descent and distribution (in which case, such transferee shall succeed to the rights and obligations of Grantee hereunder). During Grantee's lifetime, the Option shall only be exercisable by Grantee. If Grantee or anyone claiming under or through Grantee attempts to violate this Section 5, such attempted violation shall be null and void and without effect, and the Company's obligation hereunder shall terminate. If at the time of Grantee's death this Option has not been fully exercised, Grantee's estate or any person who acquires the right to exercise this Option by bequest or inheritance or by reason of Grantee's death may, at any time within one year after the date of Grantee's death (but in no event after the expiration of two years from the Grant Date), exercise this Option with respect to the number of shares, determined under Section 3 above, as to which Grantee could have exercised the Option at the time of Grantee's death. The applicable requirements of Section 4 above must be satisfied in full at the time of such exercise.

- 6. Administration. Any action taken or decision made by the Company, the Board or the Committee or its delegates arising out of or in connection with the construction, administration, interpretation or effect of the Plan or this Agreement shall lie within its sole and absolute discretion, as the case may be, and shall be final, conclusive and binding on Grantee and all persons claiming under or through Grantee. By accepting this grant or other benefit under the Plan, Grantee and each person claiming under or through Grantee shall be conclusively deemed to have indicated acceptance and ratification of, and consent to, any action taken under the Plan by the Company, the Board or the Committee or its delegates.
- 7. No Rights as Stockholder. Unless and until a certificate or certificates representing shares of Common Sock shall have been issued to Grantee (or any person acting under Section 5 above), Grantee shall not be or have any of the rights or privileges of a stockholder of the Company with respect to shares of Common Stock acquirable upon exercise of the Option.
- 8. <u>Investment Representation.</u> Grantee hereby acknowledges that the shares of Common Stock which Grantee may acquire by exercising the Option shall be acquired for investment without a view to distribution, within the meaning of the Securities Act, and shall not be sold, transferred, assigned, pledged or hypothecated in the absence of an effective registration statement for the shares of Common Stock under the Securities Act and applicable state securities laws or an applicable exemption from the registration requirements of the Securities Act and any applicable state securities laws. Grantee also agrees that the shares of Common Stock which Grantee may acquire by exercising the Option will not be sold or otherwise disposed of in any manner which would constitute a violation of any applicable securities laws, whether federal or state.
- 9. <u>Listing and Registration of Common Stock.</u> The Company, in its discretion, may postpone the issuance and/or delivery of shares of Common Stock upon an exercise of this Option until registration, or other qualification of such shares under any state and/or federal law, rule or regulation as the Company may reasonably in good faith consider appropriate.
- 10. Notices. Any notice hereunder to the Company shall be addressed to the Company, NexMed, Inc., 350 Corporate Blvd., Robbinsville, NJ 08691, Attention: Secretary, and any notice hereunder to Grantee shall be addressed to Grantee at Grantee's last address on the records of the Company, subject to the right of either party to designate at any time hereafter in writing some other address. Any notice shall be deemed to have been duly given when delivered personally, one day following dispatch if sent by reputable overnight courier, fees prepaid, or three days following mailing if sent by registered mail, return receipt requested, postage prepaid and addressed as set forth above.

11. <u>Binding Effect.</u> This Agreement shall be binding upon and inure to the benefit of any successors to the Company and all persons lawfully claiming under Grantee.				
12. <u>Governing Law.</u> The validity, construction, interpretation administration and effect of the Plan, and of its rules and regulations, and rights relating to the Plan and to this Agreement, shall be governed by the substantive laws, but not the choice of law rules, of the State of Nevada.				
IN WITNESS WHEREOF, the Company and the Grantee have executed this Agreement as of the date first above written.				
NexMed, Inc.				
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GRANTEE ACKNOWLEDGES AND AGREES THAT NOTHING IN THIS AGREEMENT, NOR IN THE NEXMED, INC. RECOGNITION AND RETENTION STOCK INCENTIVE PLAN WHICH IS INCORPORATED HEREIN BY REFERENCE, SHALL CONFER UPON GRANTEE ANY RIGHT WITH RESPECT TO CONTINUATION OF SERVICE BY THE COMPANY, NOR SHALL IT INTERFERE IN ANY WAY WITH GRANTEE'S RIGHT OR THE COMPANY'S RIGHT TO TERMINATE SERVICE AT ANY TIME, WITH OR WITHOUT CAUSE.

Grantee acknowledges receipt of a copy of the Plan and represents that he is familiar with the terms and provisions thereof, and hereby accepts this Option subject to all of the terms and provisions of the Plan thereof except as otherwise specifically stated in this Option Agreement. Grantee has reviewed the Plan and this Option Agreement in this entirety, has had an opportunity to obtain the advice of counsel prior to executing this Option Agreement and fully understands all provisions of this Option Agreement. Grantee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under the Plan.

GRANTEE

## Appendix A Change in Control

For the purpose of this Agreement, a "Change in Control" shall be deemed to have taken place if:

A. Individuals who, on the date hereof, constitute the Board (the "Incumbent Directors") cease for any reason to constitute at least a majority of the Board, provided that any person becoming a director subsequent to the date hereof, whose election or nomination for election was approved by a vote of at least two-thirds of the Incumbent Directors then on the Board (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for director, without written objection to such nomination) shall be an Incumbent Director; provided, however, that, no individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to directors or as a result of any other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board shall be deemed to be an Incumbent Director;

B. Any "Person" (as such term is defined in Section 3(a)(9) of the Securities Exchange Act of 1934 (the "Exchange Act") and as used in Sections 13(d)(3) and 14(d)(2) of the Exchange Act) is or becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 25% or more of the combined voting power of the Company's then outstanding securities eligible to vote for the election of the Board (the "Voting Securities"); provided, however, that, the event described in this paragraph B shall not be deemed to be a Change in Control by virtue of any of the following acquisitions: (i) by the Company or any subsidiary of the Company in which the Company owns more than 25% of the combined voting power of such entity (a "Subsidiary"), (ii) by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Subsidiary, (iii) by any underwriter temporarily holding the Company's Voting Securities pursuant to a public offering of such Voting Securities, (iv) pursuant to a Non-Qualifying Transaction (as defined in paragraph C immediately below), (v) pursuant to any acquisition by Executive or by any Person which is an "affiliate" (within the meaning of 17 C.F.R. § 230.405) of Executive (an "Excluded Person");

C. The consummation of a merger, consolidation, statutory share exchange or similar form of corporate transaction involving the Company or any of its Subsidiaries that requires the approval of the Company's stockholders, whether for such transaction or the issuance of securities in the transaction (a "Business Combination"), unless immediately following such Business Combination: (i) more than 25% of the total voting power of (A) the corporation resulting from such Business Combination (the "Surviving Corporation"), or (B) if applicable, the ultimate parent corporation that directly or indirectly has beneficial ownership of 100% of the voting securities eligible to elect directors of the Surviving Company (the "Parent Corporation"), is represented by the Company's Voting Securities that were outstanding immediately prior to such Business Combination (or, if applicable, is represented by shares into which the Company's Voting Securities were converted pursuant to such Business Combination), and such voting power among the holders thereof is in substantially the same proportion as the voting power of the Company's Voting Securities among the holders thereof immediately prior to the Business Combination, (ii) no Person (other than (A) any employee benefit plan (or related trust) sponsored or maintained by the Surviving Corporation or the Parent Corporation or (B) an Excluded Person is or becomes the beneficial owner, directly or indirectly, of 25% or more of the total voting power of the outstanding voting securities eligible to elect directors of the Parent Corporation (or, if there is no Parent Corporation, the Surviving Corporation) and (iii) at least a majority of the members of the board of directors of the Parent Corporation (or, if there is no Parent Corporation, the Surviving Corporation) following the consummation of the Business Combination were Incumbent Directors at the time of the Board's approval of the execution of the initial agreement providing for such Business Combination (any Business Combinati

- D. A sale of all or substantially all of the Company's assets, other than to an Excluded Person;
- E. The stockholders of the Company approve a plan of complete liquidation or dissolution of the Company; or
- F. Such other events as the Board may designate.

Notwithstanding the foregoing, a Change in Control of the Company shall not be deemed to occur solely because any person acquires beneficial ownership of more than 25% of the Company's Voting Securities as a result of the acquisition of the Company's Voting Securities by the Company which reduces the number of the Company's Voting Securities outstanding; provided, that, if after such acquisition by the Company such person becomes the beneficial owner of additional Company Voting Securities that increases the percentage of outstanding Company Voting Securities beneficially owned by such person, a Change in Control of the Company shall then occur.

## SUBSIDIARIES OF NEXMED, INC.

- 1. NexMed Holdings, Inc., incorporated in Delaware on February 28, 1997.
- 2. NexMed (U.S.A.), Inc., incorporated in Delaware on June 18, 1997.
- 3. NexMed International Limited, incorporated in the British Virgin Islands on August 2, 1996.
  - (a) NexMed International (Hong Kong) Ltd. is a wholly-owned subsidiary of NexMed International Limited incorporated in Hong Kong on March 14, 2001

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-91957, 333-46976, 333-96813, 333-105509, 333-107137, 333-111894, 333-117717 and 333-122114) and in the Registration Statement on Form S-8 (Nos. 333-93435) of our report dated March 15, 2005 relating to the financial statements, financial statement schedule, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP New York, New York March 15, 2005

#### **CERTIFICATION**

- I, Y. Joseph Mo, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of NexMed, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (b) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (c) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (d) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (e) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter, that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005\_

/s/ Y. Joseph Mo

Y. Joseph Mo Chief Executive Officer

#### **CERTIFICATION**

#### I, Vivian H. Liu, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of NexMed, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter, that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005\_

/s/ Vivian H. Liu

Name: Vivian H. Liu

Title: Chief Financial Officer

# CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Y. Joseph Mo, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of NexMed, Inc. on Form 10-K for the year ended December 31, 2004, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on 10-K fairly presents in all material respects the financial condition and results of operations of NexMed, Inc.

Date: March 16, 2005	By: /s/ Y. Joseph Mo
	Y. Joseph Mo Chief Executive Officer

# CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Vivian H. Liu, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of NexMed, Inc. on Form 10-K for the year ended December 31, 2004, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on 10-K fairly presents in all material respects the financial condition and results of operations of NexMed, Inc.

Date: March 16, 2005

By: /s/ Vivian H. Liu

Vivian H. Liu

Chief Financial Officer